

Healthcare Technologies Resource Guide

A Reference for U.S. Exporters

2016 Edition



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Introduction

What Can the U.S. Commercial Service Do for You?

The U.S. Commercial Service (CS) is the export promotion arm of the U.S. Department of Commerce's International Trade Administration. Our global network of more than 1400 trade professionals is located throughout the United States and in U.S. Embassies and Consulates in more than 70 countries. Whether you are looking to make your first international sale or expand to additional markets, we offer the expertise you need to connect with lucrative opportunities to increase your bottom line.

Our Services

The CS Healthcare Technologies Team works to address issues and trade opportunities specific to the strong and growing healthcare sector, and to ensure you have the information you need to grow your business. This resource guide is just one of the ways we can provide the information you need to set priorities and plan for business growth. To learn more about how we can help you, visit export.gov/industry/health.

For more information on how CS can help your company increase its international sales, please contact your local CS office. A list of offices appears at the back of this guide and at export.gov/usoffices.



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Global Healthcare Team Leader

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Market Intelligence

- Analyze market potential and foreign competitors
- Obtain useful information on best prospects, financing, laws, and cultural issues
- Conduct background checks on potential buyers and distributors

Business Matchmaking

- Connect with pre-screened potential partners
- Promote your product or service to prospective buyers at trade events worldwide
- Meet with international industry and government decision makers in your target market(s)

Trade Counseling

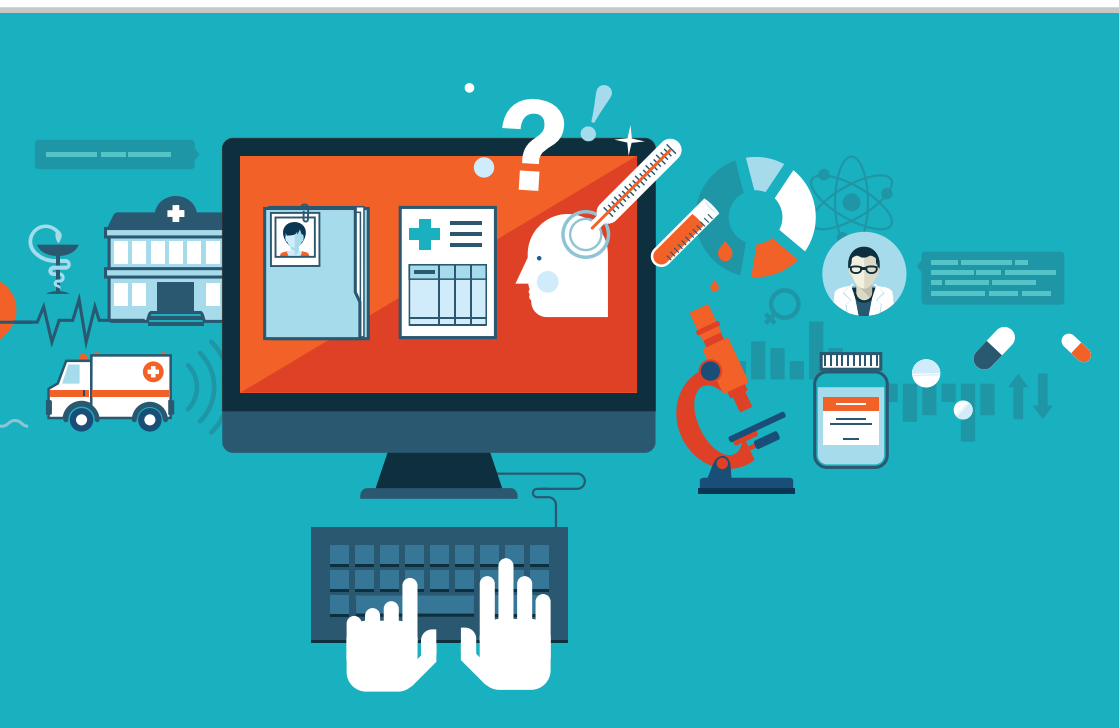
- Develop effective market entry and sales strategies
- Understand export documentation requirements and import regulations of foreign markets
- Navigate U.S. government export controls, compliance, and trade financing options

Commercial Diplomacy

- Overcome trade obstacles to successfully enter international markets
- Benefit from coordinated U.S. government engagement with foreign governments to protect U.S. business interests
- Access U.S. government trade advocacy for your foreign government procurement bids



Market Briefs



Angola

Summary

Angola is the third-largest economy in Africa behind South Africa and Nigeria. A first time national census conducted in 2014 determined a population of 24.4 million inhabitants. Angola is considered a middle-income country with GDP of USD 131 billion (2014) and GDP per capita of USD 6,300 (2014), so receives limited international donor aid.

Healthcare in Angola is divided into public and private systems. The public health service is free of charge according to Angolan law and offers basic primary healthcare to specialized health services. Angola's public infrastructure of national hospitals, municipal hospitals, health centers, and health clinics is generally insufficient to cover the population's needs. Most equipment is inadequately maintained and rapidly deteriorating and staff lack proper training.

The public system is complemented by a private system developed in recent years, mostly through investments made by the state oil company Sonangol and other private companies. Private health service providers are improving access to health care, albeit only for a small portion of the population. Luanda hosts four major private clinics: Girassol, affiliated with state oil company Sonangol; Sagrada Esperança, affiliated with the state diamond company Endiama; Multiperfil, affiliated with the presidency; and the Luanda Medical Center. Numerous small private clinics also service Angola's growing middle class. There has been a welcome and significant investment in new health infrastructure also outside Luanda. The best quality of health service is found in Luanda and other major cities like Benguela, Lobito, Lubango and Sumbe.

The government of Angola's National Development Plan for 2013–17 (PND) and a 2012–25 National Health Strategic Plan (PNDS) outline the government's goals of increasing the quality of life and increasing national productivity. The government focus is on rehabilitating and expanding public healthcare infrastructure and capacity including to rural areas as well as building healthcare professional

Statistics

Capital: Luanda
Population: 24.2 million (2014)
GDP (USD): 131.4 billion (2014)
Currency: Kwanza (AOA)
Language: Portuguese

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training. Familiarization with these plans would be beneficial for companies considering the Angolan market.

The health sector receives around 7.2 percent of total governmental expenditures, with a rate of USD 204 spending per capita. The government budget cutbacks in 2015 resulting from lower oil revenues negatively impacted healthcare together with all other spending.

Despite a significant improvement in the main global health indicators of the country over recent years, Angola's child and maternal mortality rates are among the highest in the world. At least one in five children die before five years of age, and the maternal mortality rate is 610 per 100,000 live births. A high fertility rate of 5.8 births per woman places pressure on an already struggling health system to keep up with the growing population's needs.

Angola has approximately 0.1 hospital beds per 1,000 people, a total of 3,700 doctors (about 0.2 doctors per 1,000 inhabitants), 34,300 nurses, and 6,400 diagnostic and therapeutic technicians. Cuba currently supplies about one-third (1,200) of the doctors distributed throughout 18 provinces of Angola. Other common healthcare professionals are Brazilian and Portuguese. Angolan universities produce close to 200 new medical doctors per year.

The major health concerns in Angola include malaria, typhoid, tuberculosis, infectious and parasitic diseases, respiratory and diarrheal diseases, cholera, rabies, and measles, sickle cell anemia, as well as an exponential increase in chronic non-communicable diseases. Communicable diseases still account for over 50 percent of the deaths recorded in the population and Angola registers a high number of cases resulting from road accidents. However, official HIV/AIDS rates are relatively low. Many of the current health problems are linked to insufficient access to medical coverage, a lack of well-trained medical personnel, a weak health management system, including logistical challenges, inadequate budgeting model within the health sector, poor access to safe drinking water, and poor sanitation conditions. Life expectancy is 55 for males and 56 for females.

Market Entry

U.S. companies should consider partnering with an appropriate local company to most effectively enter the market. In Angola, it is critical to have a local distributor to manage relationships, track public procurements, and handle the various and frequently-changing customs requirements and health regulations, and provide customer service to local buyers.

The U.S. Commercial Service in Angola can also assist interested U.S. companies to identify appropriate local partners, and can counsel on trade policy.

The National Directorate of Medicines and Equipment (DNME) is an agency under the Ministry of Health (MINSA) responsible for drafting the strategic planning and implementation of rules relating to the production, importation, supply, use, and maintenance of all appropriate technologies, including drugs, diagnostics, surgical materials, and other medical supplies. The

Health Inspection Office (Inspecção Geral de Saúde, IGS) is responsible for quality and safety of pharmaceutical drugs and medical devices.

Current Market Trends

Most health care treatment offered in Angola focuses on commonly occurring illnesses, and to some extent on HIV/AIDS and sickle cell anemia. Public hospitals deliver basic health care services, whereas private institutions like clinics and medical centers concentrate on specialties. For complex diagnostics and surgeries, patients travel to Namibia, South Africa, Cuba, Brazil, Portugal and Spain where they have access to more complete health care services, high quality facilities, more diverse equipment and service quality from medical personnel.

Currently, the best furnished institutions in Angola are the Luanda Medical Center and the Girassol Clinic. Both private entities have modern equipment with associated higher prices and international medical professionals.

Medical expenses are generally entirely covered by patients and are paid in cash prior to treatments. In some cases, expenditures are taken into account by companies under corporate agreements with health care institutions, whether locally or abroad.

In other cases, patients use health insurance. Most insurance companies offer several coverage levels, from general consultation to specialties such as dentistry, ophthalmology, gynecology, obstetric, pediatric, and acute surgeries, medical evacuations and repatriations. Some insurance contracts offer extended health plans that include international health treatment.

To facilitate medical related travel, the Angolan government—based on increasing partnership existing between Angolan health institutions and those across the borders—has established protocols with some countries, as for those previously mentioned, giving priority on visa issues to patients with medical emergencies.

Most health professionals in Angola work for both public and private institutions, on different schedules. Because Angola is short of medical personnel, telemedicine solutions are increasingly being used to reach populations in remote areas where there is scarcity of health care services.

Since medical consultations are expensive and majority of the population cannot afford reasonable health care service in the private, much of the population resort to self-medication or to natural remedies and/or traditional medicines, especially in rural areas. Public hospitals are free of charge but some patients also skip this option so as to avoid long waits and less quality service to receive basic attention.

Main Competitors

The Angolan government is interested in the revitalization of the pharmaceutical industry in the country. Due to the limited local manufacturing, most pharmaceuticals are imported into

Angola. Nova Angoméfrica, a joint venture involving the Angolan Ministry of Health and the private company Suninvest, had ceased pharmaceutical production during the civil war and reportedly started production again in 2013.

According to a study by The International Trade Centre (ITC), between 2001 and 2011 Angola imported pharmaceutical products from China (12.5 percent), India (18 percent), and Portugal (7 percent). The major competitors in the market are companies from South Africa, China, and the European Union.

Portuguese language labelling requirements and long-standing business ties position Portugal as a major supplier of pharmaceuticals as well as other products in Angola. Consequently, many products sold at leading pharmacies—Mecofarma, Moniz Silva, Novassol, Central, Mediang—are from Portugal and hold a CE mark. Importers of pharmaceuticals are required to secure import licenses from the Ministries of Health and Commerce.

Pharmaceuticals are distributed through pharmacies, hospitals, clinics and medical centers. The quality of products, prices, and service vary according to location.

Small pharmacies in the outskirts of major cities tend to sell unregulated, lower cost pharmaceuticals from India and China, while higher quality and fully registered pharmaceuticals are more common in urban centers. The National Institute for Consumer Protection (INADEC) is attempting to enforce registration requirements and keep non-conforming pharmaceuticals off the market to protect consumer health.

Angola relies exclusively on importation for medical equipment, devices, supplies and consumables. Medical solutions and equipment are distributed to hospitals, clinics, medical centers and practitioners through a small network of local importers and distributors. There is no manufacturing of equipment or devices.

U.S.-made medical solutions, equipment, instruments, devices, consumables, supplies, and furniture brands are well-known and valued by practitioners in Angola due to their reliability and high quality. Some U.S. manufacturers (including Welch Allyn, Hill-Rom, Accu-Scope, Abbott, Baxter, Johnson & Johnson, Beckman Coulter, and Thermo Fisher Scientific) are already selling in Angola through a regional office in neighboring country or through local importers and distributors.

The Chinese government has a bilateral cooperation with the Angolan government to build hospitals across the country. Some medium-sized units have been raised up in some provinces especially in remote areas, whereas in Luanda, a bigger health care unit was raised to attend patients at a provincial level. Therefore, Luanda General Hospital (Hospital Geral de Luanda) is fully equipped with Chinese supplies, and the medical personal is awaiting special Chinese training to fully start operations.

This newly built institution will contribute expand public health care services, that was concentrated in Josina Machel Hospital and in Pediatric Hospital David Bernardino.

Current Demand

Angola's healthcare sector holds great potential with priority to expand public health services, while private health care continues to grow to meet middle and upper class demand.

Given the size of the public health system, it is the largest procurer of medical supplies, equipment, devices and pharmaceuticals. The state budget, therefore, plays an important role. The National Health Strategic Plan (PNDS) envisions about USD 5.2 billion being invested in the public system per year, on average, for the period 2013 to 2025. The focus areas are: expansion of the health network (42 percent of the projected budget), disease prevention (39 percent), and human resource capacity building (16 percent).

As the economy grows and attracts more private and foreign investment, the projection is for the private health system to grow more rapidly than the public. The private system also has potential to expand outside of Luanda, which creates opportunities in the construction of new facilities and the supply of medical solutions including large and small medical equipment (instruments, diagnostic and imaging, that enable in-depth analysis and diagnostics), consumables, pharmaceuticals, furniture as well as training.

The Angolan Institute for Cancer Control (IACC) created to ensure the health and medical care in oncology in the public sector, as well as policy implementation, programs and plans for prevention and specialized treatment, represents a need for innovative techniques in the diagnosis and treatment of cancer.

A neurosurgery and hydrocephaly treatment center was also recently inaugurated in Luanda by sponsor, the Lwini Foundation, devoted to creating initiatives of social and philanthropic support and helping needy people, particularly children, women, and those suffering from disabilities. The neurosurgery and hydrocephaly treatment center aims at improving the conditions for corrective surgery on children suffering from spinal bifida and hydrocephaly.

The market is also experiencing a trend of comprehensive to well-furnished pharmacies being established, offering prescription and non-prescription medicines, personal hygiene, self-improvement health products, smoking cessation, first aid kit, basic outpatient immunization and diagnosis services.

The government also plans to expand health care service to rural areas and villages, as well as to the less provided population in bigger cities, who mostly resort to traditional medicine.

Luanda General Hospital (Hospital Geral de Luanda) is a newly built institution which contributes to the expansion of public health care services, that was concentrated in Josina Machel General Hospital and in Pediatric Hospital David Bernardino.



Argentina

Summary

Healthcare expenditures in Argentina have traditionally accounted for approximately 7 percent of GDP, among the highest in the region. Imports in the overall healthcare sector have been estimated to account for around 70–75 percent of the total market. The United States continues to lead the Argentine import market of medical products and equipment, and currently holds almost 25 percent market share (2014), particularly in higher-end technology products.

Argentina remains a key market for U.S. exports to Latin America. However, controls imposed by the Argentine government have made exporting goods from any country to Argentina more difficult.

Imports from the U.S. grew 5.4 percent in 2014, amounting to USD 107.8 million. During the first quarter of 2015, total imports amounted to USD 108.2 million, with imports from the U.S. accounting for USD 23.3 million. While total imports in 2015 are expected to keep similar levels as those of 2014, when they reached USD 440 million, imports from the United States may continue to grow more than total imports in 2015 and beyond.

Market Entry

Imports of medical products must be performed by an importer registered with ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica), the Argentine equivalent to the U.S. Food and Drug Administration (FDA), as a frequent importer of medical equipment. Imported products in general, appear under the name of the local registered importer who will fulfill the registration process as a representative of the U.S. company.

Statistics

Capital: Buenos Aires
Population: 42 million
GDP (USD): 540 billion (est. 2014)
Currency: Peso (ARS)
Language: Spanish

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The Mercosur common external tariff (CET) applies to imports from countries outside the MERCOSUR area (Argentina, Brazil, Uruguay and Paraguay). The CET currently averages 14 percent for medical products plus 0.5 percent in a statistics fee.

Current Market Trends

The Argentine medical equipment and device market continues to be dominated by imports. Imports increased in general in 2014, with imports from the U.S. growing slightly. Total medical equipment imports amounted to approximately USD 439.94 million in 2014, with imports from the U.S. amounting to USD 107.73 million. The United States continues to be the leading supplier of imported medical products and currently holds 24.5 percent market share, particularly in high-technology products. U.S. Import figures may continue to grow in 2015.

(For statistics, imports were based on the following Mercosur HS Codes: 84.13.19.00.1; 8413.91.90.2; 84.73.3099.910x; 85.40.71.00.100B; 90.11.10; 90.11.90.90.100; 90.12.10.10.000; 90.12.90; 90.18.10; 90.18.20; 90.18.30; 90.18.40; 90.18.50; 90.18.90; 90.19.20; 90.22.10; 90.22.20; 9022.30; 90.22.90; 90.27.90.99.200)

Main Competitors

More than 2,000 companies sell medical products and equipment in Argentina, of which 25 percent are manufacturers and 75 percent are importers. Brazil poses strong competition since imports enjoy a zero percent tariff under Mercosur. U.S., Japanese and European-made equipment is known for its high technology and precision, whereas Argentine equipment, although durable, is generally low-tech.

Domestic production has been growing, although in general it is limited mainly to lower-middle range equipment and supplies, such as x-ray devices, peripheral equipment, illumination systems, furniture, operating tables, echographs and ECGs, monitors, oximeters, cobalt pumps, incubators, anesthesia equipment, sterilization equipment, basic lab equipment, instruments for arthroscopy, fixation instruments, instruments for video endoscopy surgery, wheelchairs, and scales.

Current Demand

Niche opportunities for U.S. exports may include middle and higher-end equipment such electro-diagnostic equipment, ultrasound equipment, and other medical devices. While this report concentrates mainly on medical equipment and devices, there may be opportunities in other areas such as specialized disposables and implants, cardiovascular products, clinical laboratory equipment, molecular biology products, and diagnostic reagents.

Simpler technology is more easily financed and thus considered mass-market. In this competitive market the demand for these products is for the most part met. In any case, product potential should be determined on a case-by-case basis.

Registration Process

ANMAT, the local equivalent to the USFDA, is the Argentine agency responsible for regulating registration of medical products, biological products, dental hygiene products, healthcare sanitation and disinfectants, personal hygiene, cosmetics and perfumes, foods and dietary supplements, and medicines.

Imported medical products need to be registered with ANMAT through an authorized medical importer. The product registration process may take from 6 to 24 months.

Product classification can be: Class I, II, III and IV. Documentation required may vary according to product, and can also depend on what the ANMAT evaluator requires on each case. In general, the following documents are required:

- FDA Certificate (Certificate to Foreign Government) apostilled
- Letter or Certificate of Representation/ Distribution in Spanish with an apostille
- Users or Technical manual (in Spanish)
- ER Matrix (Essential Requirements)
- Brochures and labels

Additional documents that could be required are: electrical safety certification, manufacturing flowchart process and description; sterilization methods and parameters; scientific or clinical evidence report. Further description of ANMAT regulations on medical products can be found at www.anmat.gov.ar/principal_en.asp.

Barriers

Although Argentina remains a key market for U.S. exports to Latin America, recent controls have made exporting goods from any country to Argentina more difficult due to additional processes that Argentine importers must complete in order to import goods. It is important for would-be exporters to Argentina to confirm that their Argentine customer has all the necessary permits, such as permission to import and permission to purchase foreign exchange to pay for the import prior to shipping goods to Argentina. For additional information on these measures, please visit 1.usa.gov/1DvcWPQ.

Trade Events

Expomedical 2015

Centro Costa Salguero, Buenos Aires • expomedical.com.ar

Available Market Research

- Medical Equipment, Instruments, and Supplies (2012)
- Dental Products Overview (2011)

Despite a strong demand in the sector, medical equipment, supplies and consumables imports and sales have suffered during the first half of 2015 due to the decline in oil prices which led to an approximately 20 percent cut in the federal budget for public health. Further compounding this downturn, the lower oil revenue has led to delays for importers in securing foreign exchange. Importers of medical equipment report extensive delays in securing foreign exchange for an import transaction.

Registration Process

The Ministry of Health, under the Health Inspection Office (Inspecção Geral de Saúde, IGS) is responsible in monitoring quality of imported pharmaceuticals and medical equipment, conducting consumers' education on pharmaceutical quality, and ensuring medical devices imported into the country meet WHO norms and Angolan regulations.

All pharmaceuticals entering the Angolan market have to be registered with the Ministry of Health, submitted for laboratory tests to meet compliance to norms and standards, and have to be labelled in Portuguese. All medical devices can enter into Angola provided they are accompanied by a Certificate of Origin, Certificate of Free of Sale, and a certificate proving compliance with ISO 9001 Quality norms.

It is compulsory that the importer presents all these documents, after which a License from the Ministry of Health can be issued.

Trade Events

Mais Qualificação e Formação Especializada

November 3–6, 2015 • Luanda, Angola • multiperfileventos.com

Luanda International Fair

July 2016 • Luanda, Angola • fil-angola.co.ao/en

Medica Hospitalar

January 2016 Luanda, Angola • medicahospitalarangola.com

Resources

- Ordem dos Médicos de Angola, ordemdosmedicosdeangola.org
- Ordem dos Farmacêuticos de Angola, ordemfarmaceuticosangola.org
- Associação dos Farmacêuticos de Língua Portuguesa, www.afplp.org
- Congressos da Clínica Girassol, www.clinicagirassol.co.ao

Australia

Summary

The Australian medical equipment industry sector has consistently provided good prospects for U.S. exporters. Australia is the eighth largest market for U.S. exporters of medical products. Approximately 80 percent of medical devices and diagnostics used in the market are imports. The three major suppliers are the United States, the European Union, and Japan. U.S. medical equipment is traditionally well received due to its perceived high quality. The market is sophisticated, mature, and quick to adopt new healthcare technologies. Importers seek to obtain cost-effective and innovative products that will improve patient outcomes and reduce healthcare costs.

Market Entry

Successful market entry strategies for Australia have three common elements: understanding the market, selecting the optimal partner, and providing ongoing support to that partner. It is important to gain an understanding of the Australian context for a product or service, its competitors, standards, regulations, sales channels, and applications. Success in the market will require appointing an Australian distributor or establishing a local subsidiary, and setting up a local sales presence. Typically, distributors for medical products will cover the entire country and some may also have a subsidiary office in New Zealand. Given the size of the Australian continent—the same size as continental U.S.—and the distance from other countries, local support and service is important. Most of the criteria U.S. companies use to select distributors are applicable to Australia, with expectations adjusted to the scale of the market given the population of 23.8 million. Performing due diligence on potential local partners is just as important as in the United States.

Statistics

Capital: Canberra
Population: 23.8 million
GDP (USD): 1.525 trillion
Currency: Australian Dollar (AUD)
Language: English

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Current Market Trends

Australia has a high per capita income and there is demand for a full range of medical equipment. The USD 5 billion market is price sensitive and competitive. Australia spends approximately 9.7 percent of its GDP on healthcare, which is similar to the United Kingdom but less than the United States. Australia's ageing population will significantly influence the demand for products and products that serve the ageing population are likely to experience growth.

The growth of chronic disease in Australia is similar to that in other developed nations. Australians increasingly suffer from asthma; cancer; diabetes; obesity; heart, stroke, and vascular disease; osteoarthritis, rheumatoid arthritis; and osteoporosis. Opportunities exist for technologies that avert or reduce disability because of these diseases.

Main Competitors

Imports supply approximately 80 percent of Australia's demand for medical equipment. Key suppliers include the United States, the European Union, Switzerland, and Japan. Many suppliers in the Australian industry are subsidiaries of overseas corporations. The major U.S. medical companies represented in Australia (either through local representatives or subsidiary offices) include: 3M, Bard, Baxter Healthcare, BD, Boston Scientific, Cook Medical, Johnson & Johnson Medical, Medtronic, St. Jude Medical, Stryker, and Zimmer. U.S. companies may experience strong competition from U.S. companies or multinationals already in the market.

Current Demand

Australia's high standard of medical practice and aging population underpin a continued demand for a range of sophisticated, high quality, and innovative medical equipment. Importers seek to source cost-effective and innovative products that will improve patient outcomes and reduce healthcare costs. Opportunities exist for products that provide a significant improvement in clinical outcomes, and product with clearly differentiated capabilities. There is also a growing demand for products that lead to faster patient recovery, reduce hospital and rehabilitation costs, and alleviate or manage disability and chronic pain.

Both the public and private sectors provide healthcare in Australia; as a result, government healthcare policies and public health influence the volume and pricing of healthcare products and services. Federal and State government spending accounts for 70 percent of total healthcare expenditure. The non-governmental sector (individuals and private health insurance) funds are the remaining 30 percent. Approximately 45 percent of Australians have private health insurance.

Registration Process

The Therapeutic Goods Administration (TGA) regulates the medical equipment industry. Australia's regulatory framework is based on Global Harmonization Task Force (GHTF) and European Community guidelines. U.S. exporters must appoint an Australian representative/ sponsor to obtain regulatory approval from the TGA. U.S.-manufactured medical devices require an EC Certificate from a European Union Notified Body. Alternatively, U.S. manufacturers can apply to the TGA for a Conformity Assessment Certificate.

Further information is available at tga.gov.au.

Trade Events

AusBiotech 2015

October 20–23, 2015 • Melbourne, Victoria • ausbiotechnc.org

Resources

- Australian Government Department of Health, health.gov.au
- NSW Health, tenders.nsw.gov.au/health
- Health Purchasing Victoria, hvp.org.au
- Queensland Health, health.qld.gov.au
- Department of Human Services, humanservices.gov.au

Austria

Summary

Austria is a dynamic EU member country with an affluent population of 8.5 million German speakers. Austria's manageable size and stable business environment make it an attractive market for U.S. exporters, as well as an attractive test market for U.S. companies with an eye toward expanding into neighboring Germany. Austria's historical and economic ties to the strong growth markets of Eastern and Southeastern Europe also make it a logical base for serving those markets. Currently 330 U.S. companies have subsidiaries, affiliates, franchisees, and licensees in Austria, of which about 150 have regional responsibilities for Central European, Eastern European, or Balkan countries. U.S. products and services maintain a good reputation in Austria.

In 2014, Austrian imports of medical equipment were approximately USD 2.0 billion. For 2015 we expect these imports to show an increase to almost USD 2.2 billion. Total demand for medical devices in Austria added up to USD 1.3 billion, while exports of this equipment amounted to USD 1.8 billion. Austria is a transit-trade country with strong trade relationships with Central, Eastern and Southeastern Europe, as well as the Near and Middle East. Re-exporting products is quite common here; hence the volume of imports exceeds the total market. Taking into consideration these re-exports, imports are expected to increase at an average annual real growth rate of 8 percent. The size of the market in Austria for medical equipment should also increase by about 6–8 percent annually over the next three years.

Presently, Austria provides its citizens with universal or nearly universal medical service. Participation in public health insurance programs is essentially mandatory. Some 6.5 million Austrians contribute to the public health insurance companies (Krankenkassen), providing health care coverage for these workers and their families, or about 8.4 million persons. Insurance costs are shared between

Statistics

Capital: Vienna
Population: 8.5 million
GDP (USD): 438.2 billion (2014)
Currency: Euro (EUR/€)
Language: German

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employers and employees. Insurance for hospital treatment, however, falls short of the actual costs, and the difference has to be met from public funds.

Market Entry

U.S. companies should plan their market entry very carefully. Given its location in the center of Europe and the size of its market, small enough to allow a quick overview, Austria stands out as a desirable, affluent pilot market for advanced U.S. products. The best strategy is to screen potential distributors and select a qualified local distributor. Austrian distributors are usually knowledgeable and experienced. They regularly call on hospitals, clinics, laboratories, and medical doctors with practices. The majority of distributors are fluent in English. They are also knowledgeable about EU approval procedures and will obtain approval for U.S. suppliers if needed.

To be successful, a U.S. supplier should discuss and agree on a marketing strategy with a prospective distributor. Once the agent or distributor is selected, it is preferable to maintain this relationship for a number of years. Abrupt changes in distribution patterns distract users from trusted suppliers and have been detrimental to U.S. suppliers who have taken such action in the past. It may take up to two years to introduce a new product due to the conservative and complex nature of the Austrian market.

Current Market Trends

U.S.-made products that are on the cutting-edge will have great potential, as Austrians expect hospitals to have the latest technology. The trend, however, is to reduce the number of hospital beds and to close down some hospitals altogether. Therefore, U.S. companies that are interested in hospital construction or in the sale of “routine” hospital equipment and supplies may find their prospects reduced over the next few years.

Projected growth rates for different imaging products vary considerably. The Austrian market for medical equipment is constantly evolving and utilizing increasingly sophisticated products.

Scanning units have benefited from technological improvements since their introduction about 30 years ago. Most suppliers now offer user-friendly features like image networking, which enable the user to digitally store and project high-quality images. These products should have very good prospects in the future.

Austria is an evolving market for echographic units. This ultrasound technique continues to gain popularity as the industry discovers new applications for it. Recent technological advances have enabled manufacturers to implement Doppler technology and sophisticated probes within their designs. There is also an increasing demand for all kinds of in-vitro products in Austria.

Main Competitors

The great majority of medical equipment used in Austria is imported. U.S. manufacturers have seized a substantial share of the market and are now the second-largest supplier group, following German companies. German competition enjoys the advantages of geographic proximity, a common language, products with the same standards, no exchange rate problems, and duty-free access through Austria's membership in the EU.

Germany supplied 30.3 percent of Austria's imports of medical equipment in 2014. The United States ranked second with 16.3 percent among foreign supplier countries, followed by Switzerland with 7.2 percent, The Netherlands with 5.3 percent, China with 4.6 percent and Japan with 3.5 percent. Multiple countries supply the balance.

Total Austrian imports of medical devices from the United States amounted to USD 321 million in 2014 and should reach USD 359 million in 2015. Sales of U.S.-engineered healthcare equipment are actually much higher than are reflected in official import statistics, because many products imported into Austria from Western Europe and from the Far East were made or assembled by subsidiaries of U.S. companies.

There are currently 34 national and international producers of medical devices and equipment operating in Austria. Their products range from magnetic field systems and infusion warmers by companies like Biegler GmbH, to 3D ultrasound diagnostic apparatus by GE Healthcare Kretztechnik, to X-ray, CT and MRI systems, produced by several multinational companies.

Other products within the field of medical devices produced in Austria include dental devices, prosthetics, blood and infusion warmers, tensiometers, hygiene and maintenance units, surgical drives, power tools for the treatment of fractures, ceramic furnaces, amalgam mixers and trauma implants.

Current Demand

Several high-quality products and devices are currently in demand in Austria:

- Nuclear medical instruments (nuclear magnetic resonance scanners)
- Diagnostic apparatus including cardiology instruments, echocardiography systems, advanced electrocardiograph equipment, monitoring systems, ultrasound equipment, gynecology and urology diagnostic systems and endoscopes
- Scanners, computer tomography imaging systems, magnetic resonance imaging
- Dialysis equipment
- Pacemakers
- Sophisticated digitalized x-ray equipment
- Clinical laboratory equipment including blood cell counters, and blood gas analyzers
- In-vitro diagnostic products

The current trend is miniaturization of electro-medical devices and nanotechnology products.

Registration Process

All U.S. medical devices have to be marked with the mandatory CE (Conformité Européenne) conformity mark. With the CE marking on a product, the manufacturer ensures that the product conforms with the essential requirements of the applicable EC directives. Deviating from sector directives regulating other industrial goods, medical devices have to comply with “essential requirements” as described in Annex I of Directive 93/42/EEC. According to this, medical devices must not only be safe but must also function in a medical-technical way as described in the manufacturer’s “intended purpose.”

Barriers

Austria is a highly developed open market with relatively liberal policies and sharp competition. There are no significant trade barriers or limitations on U.S. medical devices.

Trade Events

Austria has no general medical fair. Some smaller specialized medical exhibitions are organized in connection with medical conventions. The great majority of Austrian medical importers/distributors regularly attend the most important European medical fair:

MEDICA

November 16–19, 2015; 14–17, 2016 • Düsseldorf, Germany • medica-tradefair.com

Considered the world’s most important and largest international fair for medical equipment. 130,000 trade visitors from 85 countries; over 4,600 distributors from 66 countries.

Available Market Research

- Dental Industry (2014)

Bahrain

Summary

Bahrain's healthcare sector is a government priority. Spending on products, medicines, and medical machines are forecast to reach USD 137.9 million in 2015; USD 18.5 million will be spent on health-related infrastructure development.

In October 2013, the Ministry of Health announced USD 716.2 million would be allocated from the GCC Marshall Plan to the Ministry of Health in the next 10 years. The funding will be used for eight major projects, including construction of new hospitals in central governorates, clinics, upgrading medical appliances, a genetic disease research center, and other services.

The growing market for medical equipment presents increased business opportunities for U.S. exporters.

Market Entry

Bahrain offers 100 percent foreign ownership. U.S. companies often find a Bahraini representative, though it is not always necessary. It is also advisable for companies to work with local legal counsel when drawing up a contractual agreement and establish a presence in the country when bidding on government tenders.

Due to the Free Trade Agreement (FTA) with the United States, there is no customs duty on any U.S. imported equipment.

The public sector dominates the supply of health care services in Bahrain and accounts for the majority of health care expenditures. Public health sector spending represents 7.8 percent of total government spending. All Bahrainis receive free state-funded healthcare while most companies offer their expatriate workers healthcare coverage, either through insurance companies or through arrangements with one or more local private hospitals. There is an USD 8 fee for expatriates attending an emergency clinic in a government hospital.

Statistics

Capital: Manama
Population: 1.3 million
GDP (USD): 33.9 billion (2014)
Currency: Bahrain Dinar (BHD)
Language: Arabic

Contact

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In 2015, a compulsory health insurance fee was implemented. All employers renewing work permits for their employees must pay USD 191 for health insurance for one year, and USD 383 for two years. This increased the private sector's contribution to Bahrain's healthcare system.

The Ministry of Health's Pharmacy and Drug Control Directorate monitors and controls the import and distribution of medical devices and pharmaceuticals. The Bahraini pharmaceutical market depends highly on imported drugs. Before the approval of any medicine, two other GCC countries—one being the Kingdom of Saudi Arabia—must approve it.

Morbidity and mortality statistics indicate major diseases in Bahrain include diabetes, respiratory infections, genetic diseases (sickle cell and thalassamia), and cardiovascular disease. Recent trends show an increasing rate of oncology patients, particularly breast cancer.

- Over 60 percent of the population is classified as overweight.
- Almost 20 percent of the population is diabetic.
- More than 20 percent of the population smokes regularly.

Main Competitors

The Bahraini market completely depends on imports for medical devices and pharmaceuticals. U.S. companies are present, but European and Asian suppliers are aggressively gaining market share with their close proximity to the market and competitive prices.

Current Demand

Best prospects include:

- Pharmaceutical industry and drug packaging and distribution
- Health complementary services
- Health support services and resorts
- Health education and training
- Medical research centers
- IT (E-health)
- Biotechnology
- Creating a national strategic storage facility to house an emergency supply of drugs and medicines
- Procuring an IT system that links public sector hospitals with their private sector counterparts

Barriers

Despite the entry into force of the FTA, difficulties remain for duty-free access of select goods. Customs authorities occasionally attempt to collect custom duties on some items, and there have been reports that goods which are not individually labeled "Made in the USA" do not receive the preferential treatment they are accorded under the FTA.

Belgium

Summary

Belgium produces less than 10 percent of medical equipment consumed domestically. This leaves the market open for heavy competition among suppliers from the U.S., Germany, France and U.K. According to the latest available figures, the U.S. has a 28 percent share of total medical equipment imports into Belgium. U.S. suppliers are particularly dominant in sectors of diagnostic imaging apparatus, orthopedic and implantable products and medical and surgical instruments.

The Belgian market for medical equipment and supplies is estimated at USD 2.8 billion. Over the past 5 years, this sector has seen an annual growth of approximately 4 percent. The Belgian Social Security System, which includes the Health Care System, is considered among the most extensive and efficient in Europe. It covers nearly 100 percent of the population of 11 million inhabitants.

Market Entry

Belgium is an effective starting point for marketing medical equipment to the rest of Europe due to its geographical location, its effective healthcare system, and its relatively open attitude regarding procurement. Belgium is a distribution center for many multinationals: products are imported into Belgium and exported to other European countries.

In order to enter the medical equipment market in Belgium, U.S. suppliers should be familiar with the EU directives concerning the registration, marketing, and health/safety standards required throughout Europe as well as regulations specific to Belgium. It is therefore advisable to work with a local partner/distributor.

Since July 1, 2013, the European Directive 2004/18/EC on public procurement applies to all hospitals for the purchase of medicines and medical devices. The directive requires that for purchases over the threshold of EUR 200,000 a European tender should be released and published in the supplement of the Official Journal

Statistics

Capital: Brussels
Population: 11 million
GDP (USD): 527.8 billion (2014)
Currency: Euro (EUR/€)
Language: Dutch, French, German

Contact

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of the European Union. Procurement with a threshold between EUR 85,000 and EUR 200,000 requires a tender in Belgium and publication in the Official Journal

Current Market Trends

Belgium's healthcare system is currently facing several challenges. A growing elderly population and higher health expectations have and will have an important impact on healthcare expenditures in the coming years. In this context, the government is looking at various cost-saving measures. Thus, innovative technologies and equipment offering cost savings will have a strong market potential. Orthopedic products, homecare products, obesity and diabetes products are in high demand.

Furthermore, there is a trend towards treating chronic diseases with new technologies allowing patients to stay home and minimizing the impact on their quality of life. Medical software, telemedicine, ehealth and mhealth are as a consequence sectors with a strong market potential. Belgium's current nomenclature and reimbursement system will be revised in 2015 and a legal framework will be put in place so that telemonitoring, medical apps, and wearable medical technologies can be used and reimbursed in the near future.

Main Competitors

Belgium has approximately 800 companies manufacturing or distributing medical products. The majority of these companies are small or medium-sized, employing an average of 20 to 50 people. Belgian suppliers do well in niche markets, including anaesthesia equipment, diagnostic imaging, cancer diagnosis, and teleradiology.

Belgium is home to many subsidiaries of U.S. companies such as GE Medical Systems, 3M, Abbott Vascular, Baxter, Johnson & Johnson Medical, Medtronic, Becton Dickinson, and Boston Scientific.

Current Demand

Best prospects include:

- Innovative technologies
- Minimally-invasive and non-invasive equipment
- User-friendly home care products
- E-Health
- Orthopedic and implantable products
- Diabetes products.

Additionally, there is a trend towards treating chronic diseases with new technologies, allowing patients to stay home and minimizing the impact on their quality of life.

Registration Process

The distribution of medical devices is regulated by Belgian law. Distributors of Medical devices including active implantable devices should notify the Federal Agency for Medicines and Health Products (bit.ly/190svUY).

Effective 2014, some implantable medical devices will have to be registered from bringing the product on the Belgian market to implanting the medical device. Furthermore, a databank will collect information regarding all implantable medical devices that are available on the Belgian market, allowing patients to check if an implant is registered or not.

Medical devices must bear CE marking for conformity when marketed (export.gov/cemark). Custom made implantable and non-implantable devices and devices for clinical investigation do not require CE marking. If a notified body has been involved in verifying the procedure of conformity, the CE marking must be accompanied by a four-figure number indicating the notified body.

Barriers

There are no significant trade barriers on U.S. medical devices.

Trade Events

HealthCare

October 2016 • Brussels, Belgium • health-care.be

Trade show for home healthcare products.

Available Market Research

- In-Vitro Diagnostics (2011)

Bolivia

Summary

There is significant interest in importing medical equipment and products to Bolivia. Multiple hospitals have approached the Embassy to express their interest in buying U.S. equipment. The Embassy is working to facilitate deals, promoting U.S. medical equipment with the Bolivian government at the departmental and national levels. In the future, the Embassy plans to work more closely with established medical equipment importers to encourage the importation of U.S. products.

Bolivian Medical Industry Market, 2013–14

(USD Millions)	2013	2014
Total Market Size	18.192	28.66
Total Local Production	0	0
Total Exports	0	0
Total Imports	18.192	28.66
Imports from the U.S.	5.532	11.675

Source: Bolivian National Statistics Bureau (INE)

Market Entry

Bolivia allows the importation of medical devices and pharmaceutical products. All importers of such products must comply with the regular importation duties and taxes, as well as the proper registration process. To learn more about the importation process companies may review the Bolivian customs medical imports guide (in Spanish), available at bit.ly/1oh7tTH.

Statistics

Capital: La Paz
Population: 11,410,654
GDP (USD): 30.601 billion (2012)
Currency: Boliviano (BOB)
Language: Spanish

Contact

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Current Market Trends

The Bolivian government prioritizes that all citizens have access to proper health services and medicines. Paragraphs I and II of Article 41 of the Bolivian Constitution stipulate that the State guarantee public access to medicines and prioritize generic drugs by promoting domestic production.

Since Bolivian pharmaceutical production is limited and there is virtually no local production of medical devices, Bolivia relies heavily on imported medical products. There are multiple companies that solely import medical equipment or pharmaceuticals to Bolivia.

Main Competitors

U.S. and European Union (EU) companies have traditionally dominated the importation of medical devices. However, in the last decade there has been an increase of Chinese medical device imports due to their cheaper prices and aggressive marketing. After an initial boom in Chinese equipment purchases, government institutions realized that the equipment did not last very long and did not have reasonable service or spare parts. As a result of negative experiences with Chinese vendors, several local governments decided to include a quality specification in addition to price in their purchases of medical devices.

Chile and Argentina continue to be the main manufacturers of medicines available to the Bolivian market, although the United States and EU also play a role. There are local companies producing medicines in Bolivia, and Bolivian President Evo Morales has said that there should be a state owned pharmaceutical company to produce essential medicines locally. As of the publication of this report, no such company has been established. Bolivia is not known to produce counterfeit medicines; however, imports of counterfeit medicines from Peru and Colombia have been detected in recent years. No reliable figures exist to estimate the size of the counterfeit market.

Current Demand

The extent of the Bolivian healthcare system is still very limited. During 2015, a nationwide campaign in Bolivia demanded a law that requires national, departmental and municipal governments to allocate at least 10 percent of their total budget for health (the current investment level is of around 6.7 percent). The main demand is for more doctors and more hospital equipment to detect and treat non communicable diseases such as diabetes, heart disease, cervical cancer and prostate cancer.

The winning candidates in recent elections (2014 national and 2015 regional elections) promised to invest millions of dollars in new hospitals and equipment and are being asked to comply with their pledges. The national government purchased its medical devices from several sources including China. After complaints on the quality of this equipment, the national government is rethinking its purchasing processes.

Regional and municipal governments are also purchasing medical devices. The Department of Santa Cruz spent USD 166 million on health between 2013 and 2014, and from that budget, around USD 33.38 million was invested on new medical equipment and hospital supplies in 2013. The investments include a higher budget for blood bank infrastructure, cancer treatment equipment including a new linear accelerator, a new state-of-the-art hospital wing with more than 100 beds, and digital x-ray equipment.

Registration Process

Pharmaceuticals

All pharmaceutical products, including generic, brand name, and over-the-counter, must have sanitary registrations, as established by the Pharmaceutical Law (Law 1737) and related regulations. Products must be registered with the Ministry of Health and approved by the ministry's National Pharmacology Directorate (Unidad de Medicamentos y Acreditación de Laboratorios, or UNIMED). The latter grants sale permit certificates to products approved by the U.S Food and Drug Administration.

UNIMED requires a detailed description (monographed copy) of each new product, with the exception of essential pharmaceutical products. The monograph must include the quantitative formula (specifying active ingredients), the pharmaceutical formula, the recommended dosage, expected product benefits, and possible side effects. Three samples of the product must also be provided to Instituto Nacional de Laboratorios de Salud (INLASA, the National Laboratory) so that specialists can verify content. UNIMED requires that products comply with World Health Organization and Pan-American Health Organization guidelines.

UNIMED takes an average of six to 12 months to review new products and one month to review essential products. For more information, please visit www.sns.gob.bo.

Drugs Covered by the Vienna Convention

If pharmaceutical products contain drugs covered by the Vienna Convention, importers must obtain special import permits from the Ministry of Health and Sports.

To import, manufacture, or distribute pharmaceuticals, companies must register with the Ministry of Health and Sports, a process that requires from 10 to 30 days. Imported products may be sold through established agents or distributors or through subsidiaries, although given their direct access to UNIMED, it may be easier to market products through agents or representatives. If the latter register pharmaceutical imports, they must have exclusive rights to import and be qualified to act as legal representatives.

Pharmaceutical brand names must also be registered with the National Intellectual Property Service (SENAPI, www.senapi.gob.bo).

Intellectual Property

U.S. companies should note that Bolivia does not have a law prohibiting copycat registration of pharmaceutical products. Companies may experience difficulties protecting their intellectual property rights and cannot expect chemical information to remain confidential. In June 2015, SENAPI presented to the Bolivian congress a draft law on industrial property which deals with copycat registration of pharmaceutical products, but it has yet to be passed.

Additional Considerations

Obtaining medical device registration in Bolivia also requires approval from UNIMED. The health ministry's medical device manual, the "Manual Dispositivos Médicos," as well as the Manual of Sanitary Registration provide specific guidance on how to comply with Bolivian regulatory requirements and commercialize medical devices.

There are Bolivian companies and law firms that can assist you in evaluating the Bolivian medical device regulatory framework, as it applies to the device(s) to be imported.

Importers of medical devices and pharmaceutical products should review the Bolivian medicines law (Law No. 1737), its implementing regulation (Supreme decree No. 25235), and the Bolivian Health Registration Manual, and then take into account

- UNIMED regulatory information and background
- Product assessment
- Device classification according to UNIMED criteria
- Bolivian authorized representation requirements
- Medical device registration requirements
- Medical device labeling requirements
- Costs and timelines

Barriers

There are no specific barriers for U.S. products. Importers need only to comply with the proper registration processes. Bolivian bureaucracy takes its time, so importers should take this into consideration.

Trade Events

Fexpocruz

September (annual) • Santa Cruz, Bolivia • www.fexpocruz.com.bo

Resources

- Healthcare Procurement (in Spanish), sicoes.gob.bo
- InfoSICOES (unofficial contract web portal), infosicoes.com
- Ministry of Health, www.minsalud.gob.bo



Brazil

Summary

Brazil is the largest medical equipment market in South America and should continue to expand through the next years. Brazilian medical equipment revenues in 2014 reached an estimated USD 7.0 billion, which represents an increase of 9.4 percent from the previous year in local currency. Brazil is both a major medical equipment producer and importer.

The United States accounts for approximately 30 percent of the import market, mainly by using through local agents, distributors and importers who sell to hospitals and clinics. In 2014, imports of medical/electrical equipment reached USD 4,457 million; USD 1.816 billion of implants and USD 2,717 of in vitro diagnostic reagents, according to Websetorial.

Market Entry

For medical products, it is necessary to have a local office, agent or distributor to import products from manufacturers. Because of regional economic disparities, varying states of infrastructure, and a host of other issues, it is often difficult to find one distributor that has complete national coverage. Main cities are São Paulo, Rio de Janeiro, Belo Horizonte, Brasília, Porto Alegre, Salvador, Recife and Curitiba.

Either setting up a company in Brazil or acquiring an existing entity is an investment option for Brazil. Setting up new companies is relatively complex, although the Ministry of Development has signaled a desire to simplify the process.

Companies are also joint venturing with Brazilian industries for final assembling and packaging of products. This process reduces import duties and documentations that are required for finished goods. In addition to that, Brazilian government is offering margins of preference in the public purchase of medical products for local made products.

Statistics

Capital: Brasília
Population: 202,657,000
GDP (USD): 1.73 trillion
Currency: Real (BRL)
Language: Portuguese (Brazil)

Contact

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Current Market Trends

Despite Brazil's recently economic downturn, private and public hospitals still have great purchasing power, and with continued expansion of Brazil's private health care sector, the market should grow. New opportunities for U.S. exporters abound, particularly for:

- Clinical Chemistry, Biomedical and advanced medical devices—high demand for new technologies
- Laboratory equipment—investments in Research and development, including some duties and registration exemptions
- Disposables and surgical—high consume from private and public hospitals
- Diagnostic devices and monitoring equipment—high demand for innovative products to replace bigger and more expensive equipment
- Orthopedics and Implants—high demand of imported products, despite higher sanitary requirements
- Health IT—demand in hospitals, including education, telemedicine, big data and integration systems
- Dental—Brazil has one of the highest number of dentists in the world
- Drugs, Pharmaceuticals and Nutrition Supplements—high dependency on imported products. New rules to facilitate imports of supplements. High demand for modern life products

Main Competitors

There are few high-quality Brazilian manufacturers of advanced medical products so Brazil's reliance on imports should continue for some time. Local buyers view U.S. and other foreign products (mainly Canadian and European) as having comparable quality and reliability. Thus, financing terms often become the differentiating criteria in making a sale.

Current Demand

There is a growing market for home health care products, which has increased dramatically in recent years. Home healthcare companies are increasingly viewed as good ways to cut hospitalization costs while offering better services for patients. The market for home health care products has been increasing in two digits every year and is estimated in USD 1,3 billion. Brazilian health insurance companies are responsible for paying 90 percent of the costs related to home care treatment.

In addition to the attractive size of the Brazilian medical market, U.S. exporters should consider the opportunities offered by Mercosur, and use Brazil as a “spring board” for export into Argentina, Uruguay and Paraguay. Since compulsory product registration before sale is required for all of Mercosur countries, U.S. exporters should consult a local lawyer/consultant before signing a contract with any agent/distributor.

Barriers

Medical products in Brazil are highly regulated by Anvisa, the Brazilian counterpart of FDA. All products must be registered or be notified in order to be commercialized. For products with higher grade risk, it may be necessary to have additional local certifications, international market data and even inspections in manufacturing plants.

The import system is very complex and can add up to 100 percent fees over products. For a more detailed explanation about how to do business in Brazil, please visit 1.usa.gov/1MvRySQ.

Trade Events

Reabilitacao

November 7–9, 2015 • São Paulo, Brazil • reabilitacao.com

Orthopedic and rehabilitation products.

Congresso Internacional de Odontologia de São Paulo (CIOSP)

January 27–30, 2016 • São Paulo, Brazil • www.ciosp.com.br

Latin America's largest dental event.

Hospitalar

May 17–20, 2016 • São Paulo, Brazil • hospitalar.com

Latin America's largest medical event.

Brunei Darussalam

Summary

Brunei has a small but growing medical industry. Brunei's Ministry of Health is tasked with providing free health care services for its citizens. Brunei's two major hospitals—Raja Isteri Pengiran Anak Saleha Hospital (RIPAS Hospital) and Jerudong Park Medical Center—are supplemented by two provincial hospitals, three district hospitals, and 16 smaller health posts. In May 2015, Brunei's Ministry of Health launched the Master Plan for the Health System and Healthcare Infrastructure which sets out the 20-year strategic plan for the country's healthcare system. The master plan outlines the building of a new outpatient hospital and upgrades to four existing hospitals.

Currently, Bruneians with the means to seek advanced medical services outside of the country will travel to countries like Singapore and Thailand for private medical consultations. When the Brunei medical system is unable to provide specific services to Brunei citizens locally, the government coordinates and pays for Brunei citizens to be sent overseas for treatment. As Brunei's young population ages and requires medical care, the medical industry in Brunei will be an important longer-term growth sector for Brunei's economy.

Market Entry

Brunei's population—largely clustered around the capital Bandar Seri Begawan, with other population centers connected by a well-maintained highway system—provides a ready destination for U.S. exports with low transit costs once goods arrive in country. U.S. companies should build personal relationships with local representatives and customers through regular visits or by establishing resident representation. U.S. companies can set up their subsidiary companies or branch offices in Brunei as private limited companies registered with the Registrar of Companies and Business Names.

Statistics

Capital: Bandar Seri Begawan
Population: 420,000 (est. 2014)
GDP (USD): 16.1 billion (2013)
Currency: Brunei dollar (BND)
Language: English, Malay, Chinese

Contact

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Current Market Trends

In May 2015, Brunei's Ministry of Health launched the Master Plan for the Health System and Healthcare Infrastructure—a 20-year strategic plan for Brunei's healthcare system. The Master Plan identifies seven key strategies by focusing on all health care components—service delivery, governance, human resources and workforce planning, finance, information technology and research, medical products, vaccines, technology, infrastructure, and facilities. A new outpatient hospital is to be built, and four existing hospitals will be upgraded.

Main Competitors

Main competitors are from Germany and other first-world nations.

Current Demand

Best Prospects for medical equipment and supplies manufacturing include:

- Manufacturing laboratory instruments, X-ray apparatus, electromedical apparatus (including electronic hearing aids), and thermometers (except medical)—are classified in Industry 33451, Navigational,
- Measuring, Electromedical, and Control Instruments Manufacturing;
- Manufacturing molded glass lens blanks—are classified in Industry 32721, Glass and Glass Product Manufacturing.

Registration Process

Even without a physical presence in Brunei, companies generally need a license to do business in the country. One does not need a Brunei citizen representative to do business commercially or when selling directly to the government.

Barriers

The United States and Brunei enjoy a long history of trade, dating to an 1850 treaty whereby Brunei and the United States agreed to trade freely and without barriers, under Most Favored Nation (MFN) status. Brunei is a growing market for the United States. During 2014, total (two way) trade between U.S. and Brunei increased to USD 581 million, up USD 5 million from the year before. Brunei's status as a founding member of the proposed Trans-Pacific Partnership trade agreement (TPP), and regional economic integration in the Association of Southeast Asian Nations (ASEAN), will provide enhanced opportunities for U.S. exporters to access the Brunei and Southeast Asian market as an increasingly attractive destination for U.S. exports.

Trade Events

Malaysia-Indonesia-Brunei (MIB) Medical Sciences Conference

Summer 2017 (biennial) • Bandar Seri Begawan, Brunei • bit.ly/1MowD42

Bulgaria

Summary

Following the trend since 2009, Bulgaria's healthcare budget will remain within the 4.1 to 4.3 percent range of the overall country GDP.

World Bank Bulgaria report, based on the financial plan prognosis of the Ministry of Finance for the overall 2014 country GDP and for the next program period until 2020, shows that healthcare expenditures will remain between 3.9–4.3 percent of the GDP.

There are two alternatives for the planned healthcare expenditures—pessimistic, which envisages 3.9 percent healthcare expenditures and optimistic—4.4 percent. The optimistic alternative is expected to result from the slow economic and GDP recovery up to 5 percent, while the pessimistic alternative would reflect the slowdown of the national economic development and holding the planned healthcare expenditures within the limits of the annual inflation rate.

The healthcare planned budget comes from two main sources—from the national budget and from the EU operational programs until 2020.

In 2009 and 2010 it amounted to 1.573 billion EUR and 1.329 billion EUR respectively. The healthcare budget for 2011 amounted to 1.659 billion EUR (4.2 percent of GDP). It increased to 1.875 billion EUR in 2012 and in 2013 it reached 1.607 billion (4.1 percent of the GDP). In 2014 it remained at 4 percent of GDP, amounting to 1.793 billion EUR. The healthcare budget for 2015 amounts to 1.795 billion EUR, which is 3.9 percent of GDP.

Individual segments of the healthcare market indicate a slight increase. This refers mainly to the pharmaceuticals market with a trend of 3–5 percent increase per IMS Health prognosis.

Statistics

Capital: Sofia
Population: 7,220,198
GDP (USD): 46,694,737
Currency: Bulgarian Lev (BGN)
Language: Bulgarian

Contact

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According to Eurostat data, Bulgaria's public spending in the health sector as a percentage of GDP is lower than that in other EU countries, but its rate of increase for the 2007–2011 period is the highest in comparison to the rest of the European Union.

With the implementation of the EU directive on cross-border healthcare, the way healthcare in Europe is planned and the range of providers to which patients have access could look very different in the years to come.

The directive outlines the right of patients to receive healthcare in other EU member states. Legislation that will extend patient choice beyond national borders, with significant implications for both National Health Service commissioners and providers, came into force in October 2013.

The short-term negotiations between the NHIF and market authorization holders (i.e. drug producers) appear to have concluded by the end of December 2013. However, the Ministry of Health is looking at new ways to extend these negotiations to include non-fully reimbursed drugs and increase patients' authorization to co-payment, thus providing better access to modern biotech drugs.

Healthcare coverage for Bulgarian population is universal. Practically everyone has access to healthcare services. Healthcare contributions are 8 percent of the incomes and are split among employees (called deductions—3.2 percent) and employers (called contributions—4.8 percent).

Market Entry

There are no specific challenges to the business environment which could be considered a serious threat. The institutions responsible for regulatory monitoring of market entry rules and laws are the Ministry of Healthcare (www.mh.government.bg), National Health Insurance Fund (www.nhif.bg), National Veterinary Institute (www.vetinst.bg), and Bulgarian Food Safety Agency (bah.government.bg/en).

Current Market Trends

The short and long term development of the healthcare sector in Bulgaria is strongly determined by the ongoing healthcare reform, a fundamental reform aiming at an efficient allocation and expenditure of healthcare assigned funds. Ministry of Healthcare has determined eight national priorities and 11 national policies for their achievement.

National priorities include:

- Guarantee the access of every Bulgarian citizen to quality medical services through reliable healthcare insurance
- Introduction of an integrated healthcare information system
- Improvement of the financial management and control systems
- Improvement and modernization of EMS
- Improvement of the regional policy with special attention to remote areas
- Improvement of efficiency in maternity, pre-school and school healthcare
- Development of sustainable HR policies regarding post graduate specialty and life-long study
- Putting prophylactics and prevention of socially important diseases as priority

National strategic policies for achieving the goals include:

- Improvement of the management efficiency
- Restructuring of the healthcare financial system efficiency
- Providing the necessary human resources and their level of performance
- Providing equality in access to healthcare
- Increasing public awareness to healthcare and prophylactics of chronic non-contagious diseases
- Providing efficient healthcare services to minorities and vulnerable groups
- Improvement of maternity, pre-school and school healthcare activities
- Boosting the regional healthcare providing system based on proof-evidences
- Introduction of innovations, investments and innovative healthcare technologies
- Development of the eHealth and Telemedicine
- Establishment of friendly and dialogue-based atmosphere with the civil society and patients organizations

Integrated information system is the goal of many governments. Healthcare professionals, social and business society, government institutions and NGOs have voiced their determination to introduce eHealthcare, which they believe will ensure patients' better access to quality health services and will improve value-for-money in health spending. The process began in 2012 with the development of electronic birth registers and of invasive cardiology procedures as well as with various activities associated with the development of electronic registers of medical devices and of patients with particular diseases such as persons with mental disorders. The next phase would be completion of the integrated system for data collection and processing at the national level. This integrated information system would enable exchange of information in real time. It will gather data about health services provided, the number of patients serviced, and the cost of diagnostics and treatment. The next step in

the e-Healthcare project implementation is the electronic prescription and electronic pharmacy.

The current government has announced it is interested in accomplishing some of these improvements through Public-Private Partnerships.

Dentistry

Ninety percent of dental practices are privately-owned.

Members of the Association of Dental Dealers in Bulgaria (adddb.bg) import, distribute, and provide service of dental equipment and instruments, and. They are

About 7,000 Bulgarian dentists have modern dental practices in Bulgaria (stomatoloji.bg).

Bulgaria's dentist-per-person ratio is almost twice the EU average. In Bulgaria, one dentist treats about 1,000 people, and in the EU the number is one dentist per 1,800 patients.

Some of the dental services are reimbursable, with the exception of the purely aesthetic dental procedures.

Medical Tourism

Popular services include:

- Balneology (mineral water and spa)
- Orthopedic services
- Spine surgery
- Dentistry
- Auditory system care
- Physiotherapy and rehabilitation
- Plastic surgery
- Noninvasive Procedures
- Assisted reproduction
- Weight loss therapy

Registration Process

Mandatory required certifications are the CE mark as well as some ISO standards such as ISO 9001, ISO 13485 and ISO 13795.

Few of the medical device directives are aligned to those of the EU, namely:

- Directive 90/385/EEC for implantable medical devices
- Directive 93/42/EEC for medical devices in general and
- Directive 98/79/EEC for in vitro medical devices

Barriers

There are no significant barriers to trade on healthcare related products in Bulgaria. Some tariff and non-tariff barriers are reported in the pharmaceutical market subsector by the LAWG and might be viewed in the National Trade Estimate Report when existing.

Trade Events

Bulmedica/Buldental

May 2016 • bulgarreklama.com

Medicus

June 2016 • fair.bg/en

Resources

- Ministry of Healthcare, mh.government.bg
- National Health Insurance Fund (NHIF), www.en.nhif.bg
- Bulgarian Drug Agency, en.bda.bg
- Veterinary Institute with Ministry of Agriculture and Forestry, bit.ly/1llrybW
- InvestBulgaria Agency, investbg.government.bg
- Health and Medical Tourism in Bulgaria, expatfocus.com/bulgaria-medical-tourism
- Treatment Abroad, bit.ly/1TQRK09



Canada

Summary

Canada's health care industry depends heavily on the demand created by the country's publicly funded and insured health care system. The medical device industry consists of companies that produce a wide range of products used for diagnosis and treatment of ailments, which include the following: medical, surgical and dental equipment (including electro-medical equipment and related software), furniture, supplies and consumables, orthopedic appliances, prosthetics and diagnostic kits, reagents, and equipment.

The Canadian healthcare system falls under the jurisdiction of each province and territory. While funding is subsidized through federal transfer payments, the delivery and management of healthcare services are controlled by the provincial governments. Healthcare systems in Canada use various competitive tendering processes for the procurement of medical devices and diagnostics technologies. These change depending on the province, but are generally conducted by each hospital and depend on the need and resources available to the hospital.

The Canadian medical device market was valued at approximately USD 8 billion in 2014, making it the ninth largest market in the world. Canada's medical device imports totaled approximately USD 6.3 billion in 2014. The United States is the biggest exporter of medical devices to Canada, accounting for approximately 45 percent of imports, or nearly USD 3 billion.

Currently, 80 percent of the Canadian medical device market is comprised of imported goods. There is particular demand for diagnostic equipment, as well as consumables, patient aids, orthopaedic and prosthetic equipment, and dental equipment. The orthopaedic and prosthetic equipment subsector is experiencing the strongest growth.

Statistics

Capital: Ottawa
Population: 35.75 million (est. 2015)
GDP (USD): 1.785 trillion (est. 2014)
Currency: Canadian Dollar (CAD)
Language: English, French

Contact

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There are nearly 1,500 manufacturers of medical devices in Canada, employing approximately 35,000 people across the country. The three largest markets of the industry are respectively, Ontario, Quebec and British Columbia.

Medical device manufacturers should develop partnerships with Canadian distributors to sell their products. To do this, they must obtain an establishment license and, if necessary, a device license. Imported medical devices are subject to Canadian safety and effectiveness regulations and packaging requirements. Few other barriers exist for U.S. companies looking to sell in Canada. According to BMI's Medical Device Risk/Reward Index (RRI), Canada is one of the most attractive markets in the Americas for commercializing a medical device.

Market Entry

Health Canada, under the authority of the Food and Drugs Act, regulates the sale of medical devices in Canada. Health Canada is an equivalent regulatory agency to the U.S. Food and Drug Administration (FDA). Medical equipment imports must comply with marking, labeling, and packaging requirements as described in the Food and Drug Act. In particular, instructions (operator's manual) accompanying the equipment must be in both of Canada's official languages (English and French).

Current Market Trends

Hospitals and other public health institutions are the principal purchasers of medical equipment and supplies, accounting for about 70 percent of total market demand in Canada. These organizations buy directly from manufacturers for capital equipment and use group procurement and distribution for regular medical equipment including devices, instruments, and supplies.

The demand for diagnostic equipment accounted for approximately 12 percent of the total medical devices imports in 2014, which includes technologies such as nuclear medicine cameras, MRI (magnetic resonance imaging), and CT (computed tomography). Other medical electro-diagnostic and patient monitoring equipment, including ultraviolet or infrared rays and ultrasonic scanners, will also see an increased demand. Other top contributors to the medical device import market in 2014 were instruments and appliances (8.3 percent), bougies, catheters, drains, sondes, and parts (3 percent), and artificial parts of the body (1.7 percent).

Main Competitors

The United States is by far the biggest exporter of medical devices to Canada, accounting for approximately 45 percent of the country's medical device imports. Other key import sources include Switzerland (13 percent), Germany (8.6 percent), and United Kingdom (5.3 percent).

Current Demand

The Canadian medical device market depends upon imports for about 80 percent of its consumption. The import market is expected to grow at a 4.4 percent rate through 2016. Orthopedic and prosthetic equipment imports are projected to expand at growth rate of 8.3 percent, while demand for all other medical device categories are expected to grow by at least 3 percent per year.

Canada's elderly population continues to grow. 15.7 percent of the population is aged 65 and over, and this is expected to increase to 18.2 percent by 2016. This rapid aging of the population presents a key market opportunity for companies in the medical device industry.

Registration Process

Canadian authorities have worked at harmonizing regulations with those of the United States and Europe. In keeping with international trends, medical devices are regulated under the Food and Drugs Act as Class I (low risk), II, III or IV (high risk) devices, subject to Health Canada approval. All medical devices require an establishment license, and Class II, III and IV devices require a device license. All products are subject to safety and effectiveness requirements, including Class I devices, and these requirements must be satisfied with objective, documented evidence.

Barriers

Trade in the medical device market presents a number of advantages to U.S. companies. U.S. companies benefit from similarities between U.S. and Canadian regulations concerning the safety and quality of medical devices. Other advantages include: the similarity between general business practices, the established reputation of U.S. companies in Canada, and the close geographic proximity to Canada. Partnerships with the provincial and territorial health authorities responsible for the delivery of health care services are essential for the importing success of medical devices.

Trade Events

HealthAchieve

November 2–4, 2015 • Toronto, Canada • healthachieve.com

The largest health care gathering in Canada. Conference program with educational sessions; exhibition floor hosting 350 exhibitors showcasing health care products, services, and technologies. Approximately 9,000 delegates annually.

Available Market Research

- Available at statcan.gc.ca

Resources

- Health Canada, [hc-sc.gc.ca](https://www.hc-sc.gc.ca)

Healthcare Procurement

- MERX—Canadian Public Tenders, [merx.com](https://www.merx.com)
- SEAO—Official Tendering Site of the Government of Québec, [seao.ca](https://www.seao.ca)

Government Health Plans (by Province)

- Alberta—Alberta Health, health.alberta.ca
- British Columbia—B.C. Health, www2.gov.bc.ca/gov/content/health
- Manitoba—Manitoba Health, Healthy Living and Seniors, gov.mb.ca/health
- New Brunswick—New Brunswick Health, bit.ly/1ljh1w4
- Newfoundland and Labrador—Department of Health and Community Services, health.gov.nl.ca
- Northwest Territories—Health and Social Services, www.hss.gov.nt.ca
- Nova Scotia—Nova Scotia Department of Wellness, novascotia.ca/dhw
- Nunavut—Department of Health, gov.nu.ca/health
- Ontario—Ministry of Health and Long-Term Care, health.gov.on.ca
- Prince Edward Island—Health PEI, healthpei.ca
- Québec—Régie de l'Assurance Maladie du Québec, www.ramq.gouv.qc.ca/en
- Saskatchewan—eHealth Saskatchewan, ehealthsask.ca
- Yukon—Health and Social Services, hss.gov.yk.ca



Chile

Summary

President Bachelet's 2014 declarations are quite far from being achieved. In fact, Health Minister Castillo recently reported that the public healthcare system is in crisis. The public healthcare debt has risen by 69 percent and continues to grow. Patient wait time has also increased by 39 percent. Consequently, the Minister of Health has requested additional funds to partially solve the shortages that may occur. In her state of the union speech May 21, 2015, President Bachelet communicated that she isn't happy and is looking at ways to drive initiatives that will alleviate the situation. This sector's imports decreased by 2 percent and a similar situation is expected for 2015. The slowdown in the Chilean economy is expected to impact other healthcare priorities for the current administration such as information technology and increase in the number of healthcare professionals.

The public healthcare system is comprised of 183 hospitals: 59 high-complexity, 24 medium-complexity and 100 low-complexity hospitals. In all, the public sector has approximately 26,300 beds. In the private sector, there are 109 hospitals, with approximately 11,000 beds. The uncertainties in the impact of fiscal reforms of the current administration are expected to slow down healthcare expansion projects in the private the sector.

FONASA, the government-run healthcare insurance system, covers 75 percent of the population; of the remaining 25 percent, approximately 5 percent lacks any type of insurance, and 20 percent (bordering on 2.6 million people) pay into the private sector insurance system provided by entities called ISAPRES. There are seven Isapres currently operating in the Chilean market.

Chile's Universal Access to Healthcare government program, ex "Plan AUGE," currently known as Garantías Explícitas en Salud (GES) started in 2005 and consists of government-funded subsidized healthcare coverage for (currently) 80 diseases considered to be high-incidence. The waiting line for patients in this program has reached over one million.

Statistics

Capital: Santiago
Population: 16.5 million
GDP (USD): 277 billion
Currency: Peso (CLP)
Language: Spanish

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Market Entry

U.S. medical equipment and devices are well regarded in Chile. Appointing a qualified agent or distributor is usually recommended. Chilean distributors in the medical sector are usually knowledgeable, experienced, and well-connected throughout the country. Reliable after sales support is a priority in this market. Local distributors/representatives should be experienced in selling to the public sector through the government portal, www.mercadopublico.cl.

The metric system is standard in Chile. Electric power supply is 220V 50Hz. Since the 2004 implementation of the U.S.-Chile Free Trade Agreement, medical devices, equipment, and pharmaceuticals enter Chile duty-free, provided a U.S. certificate of origin is presented to Chilean Customs. Imports to Chile, are subject to Chile's 19 percent VAT (Value Added Tax).

Mandatory registration at the Institute of Public Health is required for all pharmaceuticals. Medical devices such as contraceptives, gloves, needles, and syringes have to be quality tested.

There are 1,002 clinical laboratories along Chile, 303 are government owned through municipalities or health centers and the rest are privately owned. In Santiago, there are 312 laboratories and 22 blood centers, which account for 31 percent of the private centers to assist 40 percent of the population.

There is no local production of laboratory equipment other than some refrigerators, cold chambers and blood banks, so the market size is estimated on imports. In 2014, the U.S. was the country of origin of 31 percent of the total laboratory equipment and 37 percent of the total reagents imports in Chile.

Miniaturization and automation are boosting the growth of new equipment lines. Customers are seeking space-saving options for cutting costs. Mobility also a; therefore, portable laboratory instruments are hitting the market. Regarding reagents, the focus is on PCR.

Current Market Trends

U.S. state-of-the-art medical technology has good market potential in Chile, especially in the private sector with regular expansion projects. The Chilean private healthcare system is well regarded in the region. Private hospitals receive foreign patients for treatment on a regular basis. Some of these private hospitals have Joint Commission accreditation; therefore maintaining high standards is a permanent goal. Many Chilean physicians have U.S. post-graduate degrees and maintain regular contact with important U.S. healthcare institutions.

Main Competitors

The majority of the medical equipment present in the Chilean market is imported. Local statistical data shows that the United States has approximately 33 percent of Chile's market share, followed by Germany with some 21 percent, and China with approximately 7 percent market share. Price is an extremely important factor, especially in the public sector where

limited funds cover a large segment of the population. The private sector is also price sensitive, but is far more likely to consider recognized brands that have good quality and after-sales service reputation.

Current Demand

Best prospects include autoclaves, surgical tables, non-disposable and disposable surgical instruments, cardiology equipment including pacemakers, monitors (low and medium complexity), central monitors, ventilators, aspiration pumps, imaging equipment, trauma equipment, anesthesia instruments and appliances, hospital furniture.

Registration Process

In general, there is no health-required registration imposed on medical devices except for contraceptives, gloves, needles, and syringes that do need authorization/quality control assessment to certify its safety.

X-Ray equipment or nuclear medicine equipment does need special authorization from other government agencies: i.e. Chilean Nuclear Energy Commission and the Electricity Superintendency. Pharmaceuticals have mandatory registration at the Institute of Public Health (ISP, www.ispch.cl). ISP is the authority for pharmaceuticals, homeopathic, natural preparations with therapeutic properties, cosmetics, and pesticides for home and sanitary use. The registration has to be carried out by companies—local or foreign—legally established in Chile. Applications for registration are submitted in official ISP forms that may be downloaded from the Institute's website, in Spanish, with samples and background documents that include: application form, legal background, qualitative and quantitative formula, clinical monograph, packing or label project, draft of medical brochure, draft of information leaflet to the patient, scientific information if applicable, copy of Free Sale Certificate or Manufacturing Agreement, analytical methodology, stability study proving the efficacy period proposed in the form, quality and purity specifications for raw materials used, sterility, microbiological and toxicity reports, if applicable. Foreign documents must be duly notarized and stamped by the Chilean Consulate at the country of origin.

Barriers

Chile has a favorable import climate. There are no known barriers to U.S. medical equipment, devices, pharmaceuticals, laboratory equipment, or diagnostic test.

Resources

- Healthcare Procurement, www.chilecompra.cl
- Government Health Plans, web.minsal.cl

China

Summary

Error: Reference source not found China has been one of the fastest growing economies in the world with a GDP of 7.4 percent in 2014. Medical device market is one of the fastest growing market sectors in China, which has an average growth rate of 20 percent within the last decade. That leads to the fact that, in 2013, China surpassed Japan to become the second largest medical device market in the world.

China offers significant potential for U.S. companies interested in entering and expanding into the Chinese medical device market. In 2014, the market scale of the medical device market reached RMB 255.6 billion, an increase of 20.5 percent when compared to 2013. Among it, more than 76 percent of market demands come from hospitals. Based on the target policy set by China's Health and Family Planning Commission, 70 to 75 percent of the medical devices in Tier-3 hospitals and 66 percent of that in Tier-2 hospitals will be imported from foreign countries. With an increasingly aging population and increasing health awareness, there is a great potential for the medical device industry on the mainland.

China's medical device market is dominated by domestic suppliers, the majority of which generally lack the expertise and experience deemed appropriate by Western

Statistics

Capital: Beijing
Population: 1.67 billion
GDP (USD): 10.3 trillion
Currency: Renminbi (RMB)
Language: Mandarin Chinese

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standards. While only a few Chinese medical device companies are upgrading to provide some mid- to high-range technology and products, the high-tech large medical equipment is dominated by foreign suppliers. Compared with domestic products, imported products are better accepted by the Chinese hospitals and the Chinese view foreign medical device companies as more credible than their Chinese counterparts. Therefore, the Chinese healthcare market is poised to be explored by those foreign enterprises that have interest.

The new regulation (Order 650) was implemented on June 1, 2014. There are some modifications in the new regulation, all imported medical devices and products must be registered with the China Food and Drug Administration (CFDA). Barriers still exist for U.S. companies looking to do business in China, thus the medical device market should be approached systematically. The strategy should be part of a company's long-term goals, and possibly initiated by way of strategic alliance.

Market Entry

China's rapidly changing regulatory environment will likely have a short-term negative impact on the overall market. China Food and Drug Administration (CFDA) is the government body responsible for regulating medical devices by testing, evaluating, and giving administrative approval for medical devices to be sold in the Chinese market.

Regulations and Standards

Recently, China's State Council promulgated the Regulation for Supervision and Administration of Medical Devices (Order 650) which went into implementation on June 1, 2014. It is the revision of the old regulation Order 276 which was implemented in 2000 by the former CFDA, (SFDA). Based on this new regulation, all import medical products must be registered or notified with the CFDA through the foreign manufacturer's authorized distributor, or through its representative office or subsidiary in China. Modifications concerning product registration, including extending existing registration certificates from four years to five and Class I products require notification with CFDA. Class II and III products are required to be registered with CFDA. Additionally, all medical devices must have product description and labeling in Chinese to meet the regulation and related compulsory standards. The product manual must also state the country of origin and the detailed contact information of the distributor.

Set Up a Representative Office

A great number of foreign companies have selected to set up a representative office to manage product registration, promotion, marketing, training and support while appointing regional or local distributors for sales, actual operation, logistics and receivables with hospitals.

Set Up Your Own Trading Company

Models for establishing your own trading company do exist. For example, if you establish a FICE (short for a foreign invested commercial enterprise), it is not necessary to use a local partner. A FICE has the right to distribute in China as well as to export to foreign markets.

Designate Distributors

China is a big market, varying greatly from one region to another. China is normally divided into three major regions: north China, south China, and east China. However, it can be further divided into northeast China and mid-west China. Depending on the type of products, U.S. companies can enter the Chinese market through regional distributors that can broadly cover secondary markets but usually rely on local Tier II or Tier III distributors for sales in each locality. Direct contact with the right local distributors may give foreign companies greater control and better representation. These local distributors are also highly product or department-oriented. Selecting the “right” distributor can be an important key success factor.

Participate in Technical Seminars or Exhibit at Trade Shows

Participating in shows/events, ideally with an agent or distributor, offers new-to-market companies greater exposure. This provides networking opportunities with key contacts in their specialized field and provides direction for future market expansion.

Current Market Trends

Currently China's medical device market has two distinct categories: 1) domestic manufacturers who supply low to mid-range products, over 80 percent of the domestic manufacturers belong to this category 2) foreign-sourced, high-end products supplied by large companies like GE, Philips, and Siemens. According to the 2014 China Medical Device Industry Development Bluebook issued by China Medical Pharmaceutical Material Association, by the end of 2014 there were a total of 15,700 domestic medical device manufacturers. China's total sales volume was RMB 255.6 (USD 40.57) billion in 2014 representing a growth of over 20 percent since the close of fiscal year 2013.

The United States ranks #1 in the import medical device market, followed by Germany and Japan. These three countries represent the majority share of China's imports.

2013–14 Chinese Imports of Medical Devices (Top Three Countries)

(USD Billions)	2013	percent share	2014	percent share	percent growth
World	17.136	100	18.088	100	5.56
United States	5.918	34.54	6.059	33.50	2.38
Germany	3.132	18.28	3.183	17.60	1.63
Japan	2.210	12.84	2.313	12.79	4.66

Source: Analysis of representative HS codes from World Trade Atlas data (HS Code: 9018, 9019, 9020, 9021, 9022, 382200, 902720, 902730, 902750, and 902780)

Main Competitors

Depending on specific product type, the main competitors include EU countries (specifically Germany) and Japan. Current government policy supports and encourages medical device innovation inside China. Some domestic manufacturers such as Shenzhen Mindray and Shandong Shinva now create high-quality products and are beginning to compete against foreign suppliers in medium- to high-level technology niches.

Current Demand

China offers significant market opportunity for U.S. companies interested in entry or expansion in the China market. Due to the growing demand for access to better health services and with the government's support and investment in the establishment of a healthcare infrastructure meant to benefit every Chinese citizen.

China has about 25,509 hospitals, 52.3 percent are public hospitals. Compared with 2013, the number of public hospitals was decreased by 98 and that of private hospitals was increased by 1,137. In 2014, China announced to allow foreign investors to wholly own hospitals in seven cities and provinces (Beijing, Shanghai, Guangdong, Fujian, Hainan, Jiangsu and Tianjin), further opening up the country's fast-growing private hospital sector. Of the USD 41.3 billion medical devices sales market in 2014, 76.1 percent was taken by hospitals, and 23.9 percent were by retail markets.

The Chinese hospitals consider U.S. products to be of superior quality as well as the most technologically advanced and they particularly welcome medical equipment and products with high-technology content. U.S. companies garner nearly three-quarters of their local revenues from the tier 3 hospitals and the remainder from the tier 2 hospitals. In an effort to capitalize on China's burgeoning medical device market, U.S. companies have expanded their local presence in China while also targeting the country's rural population. At the same time, domestic medical device companies are consolidating, upgrading quality, and beginning to compete in medium-level technology niches. With the government policy to align to supporting and encouraging medical device innovations, some domestic manufacturers such as Shenzhen Mindray are growing stronger and are already competing with foreign suppliers.

Given the status of the Chinese medical device market, significant potential exists for U.S. companies interested in entry or expansion in the Chinese market. China continues its healthcare reform under the new Administration which has entered into the stage of deepening public hospital reform at all levels. Chinese government invested RMB1,007 billion (USD 167 billion) in 2014 in healthcare sector, an increase of 9.6 percent year-on-year. The total healthcare expenditure is aiming to increase from 5.56 percent occupancy of its GDP in 2013 to 6.5 to 7 percent by 2020. While the newly released State Council's guideline about pilot reform on urban public hospitals and the foreseeable cost increase after charging CFDA registration fee signal difficulties to U.S. companies, opportunities still exist for U.S. companies with high technology and quality products.

Best prospects include:

- Medical diagnostic and imaging equipment: Black and white and colored supersonic diagnostic units, sleeping monitor, digital X-ray system, MRI, CT, DR, and ultrasound equipment.
- Surgical and emergency appliances: Anesthesia ventilation systems and components, high frequency surgical equipment, high frequency and voltage generators.
- Implantable and intervention materials and artificial organs: Interventional materials, implantable artificial organs, contact artificial organs, stent, implantable materials, and artificial organ assisting equipment.
- In vitro diagnostic equipment and reagents: Clinical and diagnostic analysis equipment, diagnostic reagents, medical test and basic equipment instruments, and point of care testing (POCT).
- Therapeutic products: Tri-dimensional Ultrasonic-focused therapeutic systems, body rotary Gamma knife, simulator, linear accelerator, laser diagnostic and surgical equipment, nuclide treatment equipment, physical and rehabilitation equipment.
- Healthcare Information Technology related equipment and products: Medical software, computer-aided diagnostic equipment, and hospital information systems (HIS, CIS, and HLT).
- Medical equipment parts and accessories.

Registration Process

All imported medical devices require registration or notify with the CFDA before being sold or distributed in the Chinese market. In China, medical devices are divided into three classes depending on levels of risks similar to but different and stricter than that of USFDA. According to Order 650, all Class II and III are required to be registered with CFDA while Class I products are required to be notified with CFDA. Clinical trials are required for Class III and some Class II medical devices unless they are on the CFDA's exemption directory for clinical trials.

Generally speaking, the process is complex and time consuming. Depending on the product class, it can take one to three years after submission of all necessary documents and respective samples for testing. U.S. companies are encouraged to register their products through their authorized distributors if they do not have a representative office or subsidiary in China. The CFDA has a comprehensive system for medical device registration and inspection, including product testing and factory audits. A company is required to provide a testing report for the product conducted by a Chinese lab. The company is also required to submit a product standard according to China's "Product Regulation Standard," for CFDA's record. In addition to the service fee charged by a local company for translation and product standard compiling, the cost varies for registering a product with CFDA, which includes product testing in an

authorized Chinese lab, the technical evaluation at the CFDA's Medical Evaluation Center, and final administrative approval by the CFDA.

Barriers

Barriers exist with an uncertain regulatory environment and extensive delays in registration and re-registration of products. Additionally, pricing control, tender, and bar code systems also play a role of delaying a company's entry into the Chinese medical device market.

While reform of the healthcare sector is creating new opportunities, it has not completely opened the market to foreign companies. Despite the enormity of the market, U.S. companies face significant challenges when entering the Chinese healthcare market. Barriers include onerous pricing and reimbursement policies on pharmaceuticals and medical devices, inadequate intellectual property protection, and bureaucratic delays in registering products for sale. Numerous restrictions and an ever-changing regulatory environment add to the challenges faced by U.S. companies trying to enter the healthcare market in China.

The Chinese government has issued new policy giving more support to domestic suppliers by encouraging innovative new products inside China. Domestic manufacturers whose products are defined, by CFDA, as innovative are expected to get an expedited approval in product registration, allowing them more lead time to enter the market and to compete against foreign suppliers in China.

Trade Events

MEDTEC China 2015

September 22—24, 2015 • Shanghai, China • medtecchina.com

China International Medical Equipment Fair (CMEF)

October 18–21, 2015 • Wuhan, China • en.cmf.com.cn

Dentech China 2015

October 21–24, 2015 • Shanghai, China • dentech.com.cn/?lang=en

Dental South China 2016

March 2–5, 2016 • Guangdong, China • dentalsouthchina.com/en

China International Medical Equipment Fair (CMEF)

April 15–18, 2016 • Shanghai, China • en.cmf.com.cn

Colombia

Summary

Colombia is the 21st-largest market for U.S. medical equipment exports. During 2014, the United States exported USD 432 million in medical equipment to Colombia. The medical device market relies on imports for around 80 percent of the market.

According to Business Monitor International “the Colombian medical device market was valued at USD 1.2 billion in 2014, ranking fourth in Latin America. It is one of the world’s 10 fastest growing medical device markets. The market is expected to almost double in value in the next three years, reaching USD 2.2 billion in 2018.

The medical devices market in Colombia is expected to resume a stable pattern of growth between 2015–18. As a result, the overall 2013–18 Compound Annual Growth Rate (CAGR) is projected at 12.0 percent. This means that Colombia will remain one of the fastest growing markets in the Americas region, with the third highest 2013–18 CAGR.”

The country’s healthcare infrastructure is adequate in the larger urban areas, but is in need of modernization. The healthcare system is complex, and coverage is not yet universal. As summarized by Business Monitor International, in June 2014, the constitutional court approved health as a fundamental right by ratifying the Statutory Health Law (Ley Estatutaria de la Salud), passed by the Congress in June 2013. Of the 26 articles of the new law, the court approved 17 and the remaining nine need to be partially modified. The new law will not be enforced until the court publishes the law and the new law is approved by the President. This new law reforms the healthcare system established by Law 100 (Ley 100), issued in 1993. Sistema Unico de Acreditacion en Salud (SUAS, Unique Health Accreditation System) was launched in July 2014 to provide a mandatory system to ensure the highest standards in healthcare provision at both public and private healthcare institutions. Healthcare providers will be requested to meet the standards of the

Statistics

Capital: Bogotá
Population: 48,227,000
GDP (USD): 378.4 billion
Currency: Colombian Peso (COP)
Language: Spanish

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International Society for Quality in Health Care (ISQua). Currently, only 32 local hospitals are accredited, but many institutions are expected to join in the short term.

According to a study by America Economia Intelligence, seven of the twenty best hospitals and clinics in Latin America in 2014 were located in Colombia. In fourth place is Fundacion Cardiovascular de Colombia in Bucaramanga, in fifth is the Fundacion Valle del Lili in Cali, in seventh Hospital Pablo Tobon in Medellin, in 10th is Fundacion Cardioinfantil in Bogota, in thirteenth Centro Medico Imbanaco in Cali, in fifteenth Hospital Universitario de San Vicente in Medellin, and in eighteenth FOSCAL in Bucaramanga.

Market Entry

To successfully penetrate the Colombian market, U.S. companies should offer competitive pricing and financing. Additionally, modern technology coupled with efficient post-sales service and parts support is a winning combination.

New-to-market exporters should develop product or service information in Spanish and check to see whether their competitors already have a presence in the market. U.S. equipment suppliers are generally encouraged to find a local representative/distributor, although this is not a legal requirement for doing business in Colombia. Local companies may operate as a manufacturer's representative (sales agent), importer/distributor, or dealer, separately or all at the same time. U.S. Companies may find the use of a local sales representative useful given their knowledge of the local market, and their understanding of local regulations and import procedures.

Finally, U.S. companies are advised to be on the lookout for relevant trade events to promote their products or in order to test the market. Trade missions to Colombia have also proven to be an effective means for promoting new U.S. products.

Current Market Trends

U.S. imports enjoy the largest share of the Colombian market, accounting for around a third of all medical equipment imports. Currently the strongest competitors are China, Germany and Japan. China is quickly increasing market share. Since the implementation of the FTA tariffs on 96 percent of U.S. medical equipment exports to Colombia went from an average of 7.6 percent (ranging from zero up to 15 percent) to zero. Colombia has FTAs with leading medical device producers such as the European Union and Canada, and is in negotiations of an FTA with Japan.

Main Competitors

Colombia is a price sensitive market—prices are a major selling factor for most. Currently the strongest competitors are China, Germany and Japan. China is quickly increasing market share.

Current Demand

Best prospects include:

- Medical, surgical, dental and veterinary instruments
- Electro-diagnostic apparatus
- Orthopedics devices
- Prosthetic devices
- Diagnostic imaging equipment
- Laboratory equipment and consumables
- Ultrasound, mammography and cardiovascular equipment
- Dermatological and laser treatment apparatus and apparel (boosted by medical tourism and expanding plastic surgery demand)
- Intensive care, cardiology, neurology, and oncology related equipment

It is expected that a number of Colombia's clinical laboratories will be upgraded in the near future, which will provide an opportunity for exporters of clinical laboratory equipment. Opportunities also exist in medical, surgical, dental and veterinary instruments and electro medical equipment.

In 2014 Colombia imported medical equipment and supplies valued at USD 1.09 billion (Jan-Nov), the highest level ever. Of this total, USD 395 million (Jan-Nov), was from the United States. The medical device industry is concentrated around the capital of Bogota. Per capita spending on medical devices is average for the region. While there is some domestic capacity for manufacturing basic items, the medical device market is heavily reliant on imports, especially for more high-tech items. A few multinationals manufacture within the country.

In addition, Colombia is seriously promoting the country as a health destination (health/ medical tourism). Colombia is well known in Latin America and the rest of the world as a pioneer and leader in health services, positioning the country as one of the most attractive destinations to receive medical treatments. This becomes an important market opportunity for the United States because the success of this industry requires high quality standards, technology and infrastructure. This has led Colombian hospital and clinic management to upgrade existing facilities, adding/renewing medical equipment and providing English language training for their staff.

The best approach to enter into this market is through distributors, as companies prefer to buy from someone located in Colombia that can provide after-sales services when needed. Although distribution and sales of imported medical equipment in Colombia is handled principally through importers, distributors, representatives, and agents, an increasing percentage of materials, supplies, and equipment, is imported directly by end-users. U.S. manufacturers should maintain close contact with end-users and provide training and demonstrations so end-users can familiarize themselves with the equipment. This strategy is being used effectively in Colombia by European and Japanese manufacturers.

Registration Process

U.S. companies should be aware that medical devices require registration at the “Instituto Nacional de Vigilancia de Medicamentos y Alimentos” (INVIMA), the country’s medical device regulator. It is strongly recommended that U.S. companies process the registration under their name and not under the local distributor name, as if it is listed under the local distributor name, the U.S. Company will not be able to change or add distributors, during the lifetime of the registration, which is 10 years. Classification of devices in Colombia follows a four-tiered risk model (Class I, Class IIa, Class IIb and Class III). Colombia’s device classification scheme is similar to those of the European Union and other Global Harmonization Task Force (GHTF) systems. If the device falls into a lower-risk category in Colombia (Class I or IIa), the company may qualify for an expedited review process and achieve market entry in a shorter time.

Barriers

Although distribution and sales of imported medical equipment in Colombia is handled principally through importers, distributors, representatives, and agents, a large percentage of materials, supplies, and equipment, are imported directly by end-user companies and/or associations. U.S. manufacturers should maintain close contact with end-users and familiarize themselves with the equipment through training and demonstrations. This strategy is being used effectively in Colombia by European and Japanese manufacturers.

Market access is not easy for newcomers. The market is very competitive and many companies (local and foreign) currently sell medical equipment and products. Registration procedures can often be challenging and may pose a barrier to entry.

Trade Events

Meditech Colombia

June 28–July 1, 2016 • feriameditech.com/?stridioma=en

Supplies, services, and technological advances to foster development of the medical industry in the Andean region, Central America, and the Caribbean.

Belleza y Salud (Beauty and Health Fair)

August 19–23, 2016 • feriabellezaysalud.com/?stridioma=en

A leading health and beauty event. The latest trends, product developments, equipment, and services for the men’s and women’s beauty industry.

Resources

- Healthcare Procurement, bit.ly/1MolUpo
- Government Health Plans, bit.ly/1MIL6F1

Costa Rica

Summary

Costa Rican Medical Equipment Market, 2012–15				
(USD Millions)	2012	2013	2014	2015 (proj.)
Total Market Size	101	118	119	124
Total Local Production	10	11	5	6
Total Exports	7	12	9	9
Total Imports	98	119	121	127
Imports from the U.S.	47	53	55	58

Source: Statistics based on the following harmonized codes: 9018.110000 to 9022.90090; 9025.110090; 9402.100000; 9402.901000 to 9402.902090.

Costa Rica has a socialized healthcare system, the Costa Rican Social Security System (Costarricense de Seguro Social: CCSS, or “Caja,” as it is popularly known). This system includes 30 hospitals: 10 general hospitals, seven regional hospitals (1 in each geographic region/province), and 13 peripheral hospitals, which vary in size. 16 of the hospitals are located in the Central Valley region of the country, where about one-half of the population lives. Additionally, the CCSS is responsible for approximately 500 clinics, and approximately 1,000 small attention units with only basic equipment, known as “Equipos Basicos de Atencion Integral” (EBAIS), which provide basic medical assistance to patients in remote areas of the country.

The CCSS hospitals have approximately 6,000 beds, while there are approximately 223 beds in three private clinics/hospitals. The “Caja” buys approximately 90 percent of the medical equipment in Costa Rica. The public is very sensitive to the government’s programs in public health and encourages, almost demands, replacement of obsolete medical equipment in the principal hospitals and clinics.

Statistics

Capital: San José
Population: 4.5 million
GDP (USD): 49.5 billion (2014)
Currency: Costa Rican colón (CRC)
Language: Spanish

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There are several private hospitals and clinics in the country, mainly in the Central Valley. Hospital Clínica Bíblica (HCB) is the largest followed by CIMA Hospital, owned by the International Hospital Corporation (headquartered in Dallas, Texas), and Hospital Hotel La Católica (HCC). These three private hospitals are accredited by the Joint Commission International (JCI). The HCB is also accredited by the Medical Tourism Associations. Both CIMA Hospital and Hospital Clínica Bíblica are building new facilities in the Guanacaste Province. Hospital Metropolitano, in San José downtown, accredited by the Association for Ambulatory Healthcare (AAAHC), is the newest hospital and among their services they offer assistance to U.S. veterans, they accept medical insurance under the Foreign Medical Program (FMP) and Tricare.

The number of small, private clinics is growing constantly, as the population is demanding quicker and better health services. The largest private clinics in Costa Rica are Clínica Santa Catalina, Clínica Santa Rita, Clínica Santa Fe, and Hospital Clínica Jerusalem. The influx of foreigners, mainly from North America (U.S. and Canada), is also contributing to this private growth, in what is often known as “medical tourism.”

Market Entry

Costa Rica offers a steady and fast growing market, for medical equipment. This is due to a more mature demographic profile compared to the average in the region, a system of universal health quality and a growing number of retirees of industrialized countries that spend part of the year in the country. The level of demand for medical equipment in Costa Rica is expected to rise, as the public system, which represents 95 percent of the market, will continue replacing obsolete equipment, in virtually all categories of products.

To entry the market, U.S. companies will need to register the equipment and supplies at the Ministry of Health before sending the merchandise to Costa Rica. As part of the registration requirements a foreign company needs to find a Costa Rican representative or distributor to represent the U.S. in country.

Current Market Trends

There are several projects for the construction of new hospitals and the expansion of existing hospitals. For the period 2015–19, the CCSS has scheduled an investment of CRC 438.743 million, this according to the CCSS institutional portafolio, of which CRC 320 590 million are for infrastructure and CRC 42.305 million for medical equipment.

Major infrastructure projects scheduled for construction in 2015–19 include:

- New hospitals: Cartago, Turrialba, Golfito and Puntarenas
- Medical specialty centers: Torre This Dr. Calderon Guardia Hospital and Hospital Inpatient Tower Annexation of Nicoya
- Buildings: nutrition and ropería Dr. Calderon Guardia Hospital; National Center for Pain and Palliative Care, Rehabilitation Hospital Monsignor Sanabria (will be ready in August), Emergency Hospital of Perez Zeledon
- New operating rooms: Hospital Mexico, Hospital of San Ramon
- Equipment: scanners for regional hospitals and equipment for cancer detection for San Juan de Dios Hospital
- Health areas: Santa Cruz Naranjo, Mora-Palmichal, Barva, Buenos Aires
- EBAS: Cristo Rey, Grecia, Hojanca, Nicoya

Main Competitors

The market for imports of medical equipment in Costa Rica is comprised of mainly four countries, representing 65 percent of these imports. The United States is the largest exporter with 45 percent (approximately USD 121 million) of total imports of medical equipment in Costa Rica. Germany (USD 13 million), China (USD 7 million) and Japan (USD 4 million) are the next three largest exporters of medical equipment to Costa Rica. It is important to note that Germany has a steady growth in the amount of medical equipment exported to Costa Rica.

Current Demand

The market size for medical equipment and supplies has remained relatively stable during 2013 and 2014. In 2013, the market size amounted to USD 118 million. In 2014 it amounted to USD 121 million, an increase of approximately 3 percent from 2013. The United States is the largest exporter of medical equipment to Costa Rica, with USD 55 million in 2014 and USD 53 million in 2013. This volume represents a market share of approximately 45 percent each year of total Costa Rican imports. Major competitors to the U.S. in medical equipment, are China, Germany and Japan.

The Costa Rican Institute of Social Security (CCSS, foros.ccss.sa.cr) is the second largest government entity that requires products and services for their operations (drugs, pharmaceuticals, medical equipment, and supplies) The CCSS publishes requirements for all the public hospitals (10), clinics (500) and small medical units with basic equipment (1000).

Registration Process

The Costa Rican Ministry of Health accepted a petition submitted by U.S. Embassy San Jose to recognize U.S. Food and Drug Administration (FDA) authorizations of medical devices to be sold in the U.S. market as permissible for sale in Costa Rica without additional evaluation on the part of the GOCR. This decision—the result of three years of work—will benefit U.S. exporters of medical devices. Since all medical devices shipped from the U.S., will no longer be required to undergo additional clinical trials or obtain additional documentation (with the exception of a Certificate to Foreign Government, issued by FDA stating that the product is sold freely in the U.S. market and the plant follows good manufacturing practices), U.S. exporters will enjoy lower cost-to-market and significantly faster time-to-market. Costa Rican patients will also be able to benefit from state-of-the-art medical devices and the improved medical care that will result from their use. The market in Costa Rica for medical devices is growing and the United States is the largest exporter of this type of equipment to Costa Rica.



Croatia

Summary

In July 2013, Croatia became the 28th member of the EU. On the accession date new medical device legislation was introduced, replacing the previous Medical Devices Act of 2008.

According to the data provided by the World Health Organization (WHO), Espicom estimates that Croatia spent an estimated 8.4 percent of GDP on healthcare in 2014, equal to USD 4.7 billion, or USD 1,087 per capita. Around 5 percent of this was spent on medical equipment. Most of the medical equipment in Croatia is imported from EU countries and the United States.

Orthopedics and prosthetics, and diagnostic imaging are product areas with the best prospects. Health IT sector will also present great opportunities in the upcoming years.

Market Entry

Medical equipment products exported to Croatia must include:

- CE mark
- Directions for use in the Croatian language.

The EU common Customs Tariff schedule applies to products exported from non-EU countries. All products, regardless of origin, are subject to the value-added tax (VAT). For medical products embedded in body by surgical procedure and medical products substituting physical disabilities the VAT is 5 percent, and for all other medical products 25 percent.

The institutions responsible for regulatory monitoring of market entry rules and laws are the Ministry of Health (www.zdravlje.hr/en), the Agency for Medicinal Products and Medical Devices (almp.hr/?ln=en), the Agency for Quality and

Statistics

Capital: Zagreb
Population: 4.475 million
GDP (USD): 87.67 billion
Currency: Kuna (HRK)
Language: Croatian

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Accreditation in Health Care and Social Welfare (aaz.hr), and the Croatian Institute for Health Insurance (www.hzzo-net.hr/en).

Small purchases of medical equipment and supplies are usually made directly by hospitals and local health authorities, while for larger items; a tender is issued by the Institute for Health Insurance. The appointment of a local distributor will therefore be essential, to navigate the tendering process and reach end-users throughout the country. Some of the leading local distributors are Medika (medika.hr/en), Medical Intertrade (www.inel-mt.hr), and Phoenix Farmacija (www.phoenix-farmacija.hr/en).

Current Market Trends

In 2014, the Croatian market for medical equipment and supplies was estimated at USD 214.3 million, or USD 50 per capita, primarily government funded. The largest product area within the market was consumables, accounting for 27.7 percent of the overall total, followed by diagnostic imaging with a market share of 13.5 percent. Approximately one-fourth of this market is new medical equipment. It is expected that the market will expand at a rate of 5.0 percent per year, reaching USD 295.6 million by 2018.

The government aimed to bring the performance of the healthcare system into line with that of other EU member states through the National Health Strategy 2006–11 and National Healthcare Development Strategy 2012–20. Health IT is an important part of the strategy, and some of the goals have already been achieved—the implementation of a prescription system, followed by an e-waiting list, and a centralized information system. Even though informatization of healthcare has been in place for 10 years, it is expected that it will be fastened with use of EU structural funds now available to Croatia. The strategy also anticipates the reorganization of health institutions, integrating local clinics, family practitioners, hospitals and specialized hospital services. One of the projects is construction of new facilities at the Clinical Hospital Centre Rijeka through private-public partnership that will be worth USD 500 million. The new hospital will contain 1,000 beds, as well as polyclinic, diagnostic and therapeutic facilities.

Main Competitors

Croatia has a small domestic production sector and there is very little multinational manufacturing activity.

Around 92 percent of the medical device market is supplied by imports. Market leaders are European and U.S. manufacturers, namely General Electric, Johnson & Johnson, 3M, Bauerfeind, Astra, and Drager. Some of these companies have established their own local subsidiaries, while most companies will use third party distributors to supply the market.



Current Demand

Croatia imported medical devices valued at USD 210 million in 2014; this represented an increase of 6 percent compared with 2013. Croatia has a small domestic production sector, supplying both the domestic market and other countries from the former Yugoslavia. Imports fell in all products areas except for consumables and dental products. Even though imports have fluctuated in recent years, the general trend has been upward, from USD 109.2 million in 2002.

Funding for healthcare in Croatia is principally through the compulsory health insurance system. It was introduced in 1993 and is operated by the Croatian Institute for Health Insurance (HZZO). The HZZO collects contributions from the working population and the government makes payments on behalf of those exempt, such as the elderly, the unemployed and dependents. The USD 4.46 billion budget of the HZZO provides treatment for approximately 4.36 million insured persons annually in 49 public health centers, 22 general hospitals, 12 clinics, 40 special hospitals and 363 polyclinics.

Total spending on medical equipment, surgical instruments, accessories, laboratory equipment and various supplies in Croatian hospitals amounts to USD 208 million, of which approximately USD 45 million is spent on medical equipment. Clinical centres in Zagreb and Rijeka are the most active buyers. The most prospective product areas of the medical device market are orthopaedics and prosthetics, diagnostic imaging, and consumables.

Registration Process

The Agency for Medicinal Products and Medical Devices (HALMED) is responsible for placing medical equipment on the Medical Devices and Homeopathic Products Register. All applications submitted to HALMED are preceded in accordance with EU legislative. In order to register a medical device, manufacturers should submit a written application to HALMED, accompanied by the extensive documentation.

More information on the registration process is available at almp.hr.

Barriers

Companies exporting medical equipment to Croatia will not encounter any direct trade barriers or quotas. Non-tariff, indirect trade barriers could include the complex system of approving for government subvention list or inefficiency of the health-care system causing long delays in payments to the suppliers.

Resources

- Healthcare Procurement, eojn.nn.hr/oglasnik
- Government Health Plans, bit.ly/1MnsjBe

Cyprus

Summary

The Republic of Cyprus is moving forward with plans to reform its health care system, including bringing its public and private health care under the umbrella of a new National Health Insurance Scheme. Cyprus is the only EU member state without universal health coverage and as part of its Memorandum of Understanding with the Troika (IMF, European Commission, and European Central Bank) is required to implement national coverage. Full implementation of the new system was expected in mid-2016, but a delay with the software application has thrown the schedule off track, and is now expected for “sometime in 2017.” The changes may open new commercial opportunities for U.S. health-related products and services.

The Ministry of Health (MOH) is responsible for the overall management and oversight of Cyprus’ public health care sector, which is centralized and funded through the central state budget. The approved health care budget for 2015 is EUR 532.7 million, an increase of 0.4 percent compared to 2014.

Cyprus does not have a domestic medical device manufacturing industry and thus all medical devices are imported. According to the latest report on Cyprus by Emergo Group (a leading consultancy in medical devices), about 90 percent of medical devices are imported from EU countries including (non EU manufactured) medical devices that are re-exported from EU countries to Cyprus. In 2014 and as a result of the economic downturn that began in 2012, a drop of about 12 percent in imports has affected the market size of medical disposables and medical devices in public and private sectors, bringing down the numbers to EUR 35.2 million and EUR 10.6 million from EUR 40 million and EUR 12 million respectively. The sectors are expected to pick up as a result of the current restructuring efforts.

Statistics

Capital: Nicosia
Population: 1.20 million
GDP (USD): 23.27 billion (2014)
Currency: Euro (EUR/€)
Language: Greek, Turkish, English

Contact

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Market Entry

As a member of the EU, Cyprus' local legislation concerning medical devices complies with relevant EU directives: active implantable medical devices 90/385/EEC, medical device 93/42/EEC and in-vitro medical devices 98/79/EC as well as all the supplemental EU directives over the years. Medical trade is duty-free within the EU, as are most of the products coming from non-EU countries. Manufacturers from non-EU countries have to identify an EU-based authorized representative unless the manufacturer has a registered company in the EU. The representative serves as the point of contact for the appropriate authorities in Cyprus and can serve purely as an administrative agent or as an importer/distributor. A product for final sale or use in Cyprus should be marked with the CE identification. To affix the CE mark, the device has to be in conformity with the general requirements contained in the first annex of the three directives on medical devices. If a medical device is correctly marked as CE, it does not need additional approval or certification to be marketed throughout the EU. Furthermore, depending on the medical product, some requirements might be in place in relation to the language of the device information.

Current Market Trends

The Department of Electronic Communications (DEC) of the Ministry of Communications and Works, with the guidance of the Advisory Committee for Information Society, has developed a comprehensive "Digital Strategy (DG) for Cyprus" for the period 2012–20. The strategy promotes the use of Information and Communication Technologies (ICT) in all sectors of the economy and society including health. The overall vision of the DG for Cyprus on health includes but is not limited to:

- Install and operate in all public hospitals the Integrated Health Care Information System that covers the key elements of the hospital procedures in order to control both quality of service to patients and hospital cost
- Install and operate the drug management system in all hospitals
- Create regional health networks to exchange information between all health care providers
- Create an Internet portal to provide private physicians access to patients' electronic health records
- Design and implement an Ambient Assisted Living (AAL) program
- Use Telemedicine

Main Competitors

U.S. exporters' main competitors include companies from Germany, France, Japan, and China. Other competitors include United Kingdom, Italy, Sweden, Switzerland, Netherlands, Poland, and, more recently, Brazil and Turkey.

Current Demand

Cyprus' restructuring program under its 2013 Memorandum of Understanding with the Troika, calls for far-reaching reforms within the country's health care sector, including the process of switching to a National Health Insurance Scheme (NHIS) that will cover all citizens through both the public and private sector, make public hospitals autonomous, and introduce information technology systems in all public hospitals and health centers. Tenders for the implementation of the NHIS are expected within the next two years. The tenders will call for applications for electronic medical record systems, health care information systems, business intelligence for health, electronic content management, and decision support and knowledge management. Tools will include software and hardware devices as well as equipment.

Registration Process

Cyprus joined the EU in 2004 and has since adapted its national legislation to abide by EU law. In accordance with relevant legislation, the authority for the implementation of regulations related to medical equipment is the Medical Devices Competent Authority of Medical and Public Health Services. The duty of the Competent Authority is the development and operation of all necessary mechanisms so that medical devices are correctly registered and safely placed into the Cyprus market. The medical devices sector includes a wide variety of products ranging from bandages and syringes to more sophisticated products which incorporate advanced technologies such as nanotechnology and tissue engineering. Please refer to the "Market Entry" above for a full explanation of the registration process.

Barriers

There are no restrictions on imports in Cyprus, as long as they comply with EU regulations. Import climate is open to equipment that is innovative and of good quality.

Trade Associations

- Ministry of Health, bit.ly/1DKpiJz
- Health Insurance Organization, www.hio.org.cy/en/index_en.htm
- Purchasing and Supply Directorate, bit.ly/1IWtQZa
- Treasury—Public Procurement Directorate (eProcurement), eprocurement.gov.cy
- Cyprus Medical Devices Competent Authority, bit.ly/1hvlxMX
- Department of Electronic Communications, bit.ly/1rXbnlS
- Medical and Public Health Services, bit.ly/1zEs9h5

Czech Republic

Summary

The health care sector is very active and prominent in the Czech Republic. Czech healthcare system reform has been one of the most important political topics. The system is predominantly financed by the public sector through mandatory insurance. In 2013, healthcare expenditures reached USD 11.636 billion (CZK 290.9 billion). Most of the amount was covered through the healthcare insurance and other public sources. Private expenditures accounted for only 15.3 percent. The market has proved generally resilient to the economic downturn. Although the government is examining ways to reduce healthcare expenses, including limiting purchases of expensive equipment and pharmaceuticals or adopting e-tenders, which would procure equipment via tenders based solely on the cost of the equipment, the Czech Republic offers strong opportunities for medical device companies. About 7 percent growth is expected in the sector over the next two years.

Market Entry

A recommended strategy for a U.S. company interested in penetrating the Czech market would be to find a local partner/representative or open an office in the country. Without a local representative who can support everyday contact with customers and government representatives, it is very difficult to succeed in the market. Although products may be manufactured in accordance with international standards, it may still be necessary to localize them for use in the Czech Republic.

Current Market Trends

One of the most basic issues facing healthcare in Czech Republic is the spiraling cost of healthcare. Current market trends reflect increasing life expectancy and unhealthy lifestyles (obesity and heart disease are on the rise). Devices used to monitor symptoms and manage disease are in increasing demand. The most

Statistics

Capital: Prague
Population: 10.6 million
GDP (USD): 208.8 billion
Currency: Czech Crown (CZK)
Language: Czech

Contact

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common cause of death is circulatory system problems (heart disease, stroke, etc.). Czechs continue to be heavy smokers, and the air in many industrial cities is somewhat polluted. Growing interest in joint Czech-U.S. projects in the health care field could generate new opportunities for U.S. medical equipment providers.

Main Competitors

The Czech Republic has a small but skilled medical device manufacturing sector. Local producers focus on exports. Although domestic manufacturers are increasingly competitive, the majority of medical devices used in the Czech Republic are imported. Around 80 percent of the medical device market is supplied by imports mainly from the U.S. and European Union countries. Germany and U.S. were the leading suppliers, accounting for almost 50 percent of all imports.

Current Demand

In the Czech Republic the best market opportunities exist for cutting-edge, high-quality sophisticated medical equipment, especially equipment that increases efficiency and reduces occupancy rates in hospitals. Products, such as the following, have the best sales potential in the Czech market: mini invasive surgery systems (MIS), patient monitoring systems, video endoscopes, digital image processing, high-end ultrasounds, and home-care equipment.

Registration Process

The Czech Republic requires CE mark for most of the medical devices (exception represent custom made devices and such) sold in the market. On April 1, 2015, the new legislation on medical devices came into effect in the Czech Republic. The law introduces more extensive and stringent regulatory duties. The law creates a new Register of Medical Devices where manufacturers, importers and distributors are to be registered. Past obligation to notify the Ministry of Health when introducing new product to the market is replaced by an obligation to notify the State Institute for Drug Control (SUKL).

Barriers

The Czech Republic is a highly developed, open market with liberal policies and intense competition. One of the challenges manufacturers and importers of medical devices and pharmaceuticals will face is getting the product on the reimbursement scheme that is covered by the insurance companies. This can, in some cases, be a time consuming process. Also, products from non-EU countries are subject to import duties. Customs duty rates are updated annually and are harmonized within EU countries. The import duty for medical device depends on the specific product and matching HS code. In general, duties range on average from 0–5 percent. Medical devices and pharmaceuticals are also subject to a value added tax (VAT). Electrical installations in the Czech Republic operate on 50 hertz cycles; power is supplied at

the rate of 220V (single phase), and 220V and 380V (triple phase). More than half of Czech company representatives are able to communicate in English or in German.

Trade Events

Pragomedica + Nonhandicap

Prague, Czech Republic • incheba.cz/veletrh/pragomedica.html

Pragodent

Prague, Czech Republic • pragodent.eu/en.html

Opta

Brno, Czech Republic • bvv.cz/en/opta

Medical Fair + Rehaprotex

Brno, Czech Republic • bvv.cz/en/medical-fair-brno

Denmark

Summary

Healthcare is an important part to the Danish welfare system. A fundamental principle of the system is that all citizens have the right to good health and healthcare on equal terms, regardless of income. The result of this policy is a healthcare system that experiences very little inequality and is heavily financed by public funds (85 percent).

The healthcare sector has three political and administrative levels: the government, the regions, and the municipalities (national, regional and local authorities). Denmark is divided into five regions and 98 municipalities that cover at least 20,000 inhabitants each. The regions are responsible for providing hospital care, taking on tasks such as owning and operating hospitals, and prenatal care centers. They allocate finances for General Practitioners (GPs), specialists, physical therapists, dentists, and pharmacies. The municipalities are mainly concerned with preventive care, rehabilitation, and long-term elderly care. Danes are generally satisfied with their experiences with public services. Out of those polled, 89 percent stated they were very or somewhat satisfied when using services like consulting a General Practitioner.

Nearly 5.2 million Danes, 93 percent of the population, contact their doctors annually. Approximately 1.1 million are admitted to the hospital for inpatient care and over 11 million outpatient procedures are conducted each year. While the number of hospitals in Denmark have decreased in the past decade, the number of hospital visits increased, bringing facilities near capacity and providing incentives for more efficient methods of treatment.

As of 2015, Denmark's health sector has 54 public health facilities with 107,078 full-time employees. Over the next decade, approximately 7.1 billion USD will be invested in 16 new (or renovated) modern hospitals, eight of which will be super hospitals. In 2014 all hospitals received final approval.

Statistics

Capital: Copenhagen
Population: 5.6 million
GDP (USD): 297.359 billion (2015)
Currency: Danish Krone (DKK)
Language: Danish

Contact

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Market Entry

The World Bank ranks Denmark as the fourth-easiest country to do business in the world. According to the Economist Intelligence Unit, Denmark, over the next four years, will be the eighth best place to do business in starting in 2015. In addition it will also be third on a regional level. These findings are based on Denmark's pro-business policies, structural reforms to enhance labor market stability, and a fiscal policy that preserves the large amount of public services while achieving budget surpluses. Additionally, Denmark's flexible labor market and highly educated workforce are particularly attractive to companies.

Recommended entry modes vary with the different subsectors and nature of the product. The sale of medical devices is typically accomplished with a traditional distribution model, whereas pharmaceuticals and health IT products may require a local presence or a strategic partnership with a local vendor. For the biotech sector, strategic proximity to the local pharmaceuticals sector may also be the best solution, possibly by being co-located with a university or other research institution. For further guidance, contact a local trade specialist.

Current Market Trends

The government accounts for more than 75 percent of healthcare expenditure, and the public sector of health expenditure was USD 28.35 billion in 2014. Total health care expenditure has expanded faster than the GDP over the past decade and accounted for 11 percent of the GDP in 2014. According to the World Health Organization (WHO), health care expenditure is forecasted to increase from 2015 onwards. Approximately 18.6 percent of Denmark's population is 65 or older and nearly one-third of hospital expenditure goes to this segment. The population is expected to increase from 5.6 million in 2015 to 5.87 million by 2024, which also includes the percentage in the increase of the aged population. By 2050, it is predicted that one in every four Danish citizens will be over 65. Thus, Denmark will face future challenges regarding expected increases in healthcare costs as the population continues to age.

In 2013, the Danish government announced plans to restructure the national health system. These plans involve consolidating services into fewer, larger clinics and hospitals, transforming inpatient procedures to outpatient procedures, and tackling health inequalities in an effort to reduce cost and increase efficiency. The new hospitals represent the largest capital investment ever made in Denmark, 20–25 percent of which will be spent on IT and technology. The largest project, the NUH at Aarhus, will be the size of a provincial town, expanding Aarhus University Hospital with a budget of USD 1.1 billion.

While total healthcare spending is projected to increase in the next several years, the percentage of public health expenditure is projected to decline; however, technology and innovation will be spending priorities. The government has focused on telemedicine projects in areas like pregnancy, diabetes, and inflammatory bowel disease. They also seek to achieve more cost efficient goals. Denmark is also one of the world's leading countries in the use of eHealth (health care technology). Virtually all primary care physicians have electronic medical

records with full clinical functionality. Practitioners use Electronic Medical Records (EMR) and Electronic Prescribing to exchange clinical messages (EDI) using the MedCom network. The Danish government will prioritize a further 15 billion Danish kroner (2.25 billion U.S. dollars) over the next five years to improve healthcare and create a better old age for the elderly. As such, the government will allocate additional funds for new cancer drugs, increase hospital capacity to treat cancer and recruit doctors in charge of the sickest patients from 2016 onwards to ensure that the objective is met. The government will take new steps such as new funding to increase the capacity of medical and geriatric hospital wards and strengthened regional and municipal cooperation, to ensure better care and treatment to the growing number of elderly and people with chronic disease. Furthermore, Denmark is entering into joint research projects with India in the field of human health science biotechnology

Of total health expenditure, 14.7 percent is privately sourced. The majority of privately sourced funding is paid by patients out-of-pocket; less than 2 percent of total health expenditure comes from private health insurance. This is in part due to the reimbursement schemes the government makes available to the population. The majority prefer the referral system, which is free of charge. Only a minority uses the second option, in which the patient does not need a referral to visit specialists, but must cover extra costs incurred themselves or with additional insurance. All patients are reimbursed for pharmaceuticals, but patients must pay some user charges for healthcare such as dental care, long-term nursing, physiotherapy, and pharmaceuticals. There has been an increase in private health insurance (voluntary health insurance or VHI) for this reason. Complementary insurance is taken out by 33 percent of the population, and supplementary insurance is commonly offered by employers to their employees. Sygeforsikringen “danmark” is the single major private, non-profit, health insurance company and has approximately 2.3 million members.

Main Competitors

Denmark has many local manufacturers that possess fair shares in the global market. They specialize in the production of hearing aids, diagnostics, and orthopedic and prosthetic devices. Denmark is home to major companies in the medical device, biotech, and pharmaceutical industries, including Ambu, Bavarian Nordic, Coloplast, GN ReSound, H. Lundbeck, Novo Nordisk, Oticon, and Widex. About 90 percent of local production is exported.

Current Demand

In 2014, the average life-expectancy in Denmark has risen to 78.5 years for men and 82.7 years for women, which is among the lowest in Europe. The increase in the average life-expectancy can partly be explained by the low rate of flu epidemic in the last period. Yet, the low life expectancy may also be explained by Denmark's medicine expenses per capita are among the lowest in Europe. Lastly, lifestyle factors such as high consumption of tobacco and alcohol may help explain the numbers. While these factors negatively affect Denmark's life expectancy,

other characteristics of the population are healthier than average. For example, Denmark's rate of obesity and diabetes are among the lowest in the OECD.

In 2013, the most common cause of death in Denmark was cancer (28.5 percent). Heart disease was (13.3 percent). Other common causes of death are cerebrovascular diseases (6.1 percent), bronchitis and asthma (6.6 percent), and mental disorders (5.9 percent).

It should be noted that since healthcare in Denmark is free, Danes are very reluctant to spend money on healthcare and treatment themselves, resulting in only 14.7 percent of health expenditures coming from private sources. Nevertheless, most Danes are concerned about their health and are willing to spend money on preventive measures including healthy food, dietary supplements, and gym memberships.

Barriers

All products sold in Denmark must have the CE mark. All medicines including herbal remedies, strong vitamins, and powerful minerals must be authorized by either the Danish Health Medicines Authority, Sundhedsstyrelsen (SST), or the European Commission, which requires documentation of the effect, safety, and quality. The summary of product characteristics (SPC) is the basis of patient instructions leaflets and provides a framework for permitted advertising. The SPC for authorized medicines is available at www.produktresume.dk or via European Medicines Agency. Under special circumstances, the SST may withdraw authorization.

Unlike manufacturers and authorized representatives based in Denmark, manufacturers and authorized representatives based outside Denmark are not required to register with the SST. As of September 1, 2013, distributors and importers based in Denmark are required to register with the Danish Health and Medicines Authority; however, Danish manufacturers and representatives representing manufacturers outside of Europe are not required to do so. Required forms may be found on the website of the Danish Health and Medicines Authority (sundhedsstyrelsen.dk/en). There is a price to register, as well as an annual fee.

The SST issues Certificates of Free Sale to Danish manufacturers with a registered place of business in Denmark, requiring that the manufacturer be responsible for the design, manufacture, packaging, and labelling of a device before it is placed on the market. A CE-marked device issued a Certificate of Free sale may be manufactured and sold in Denmark without approval from the SST.

All labeling and instruction manuals must be available in Danish (e.g., inserts). Software, service manuals, displays, buttons, and keys do not have to be translated. The manufacturer, however, must define information necessary for using the device safely and symbols must be explained in the instructions. The SST may grant exemptions in certain cases for a limited period of time depending on the professional and linguistic qualifications of the user, the characteristics of the device, and if alternative products are available on the market.

Information on applying for exemptions may be found on the SST website, in addition to suggested translations and other resources.

Trade Events

European Congress for Integrative Medicine

September 25–27, 2015 • Copenhagen, Denmark • bit.ly/1VB2sJZ

eHealth Observatory

October 6–7, 2015 • Nyborg, Denmark • 2015.e-sundhedsobservatoriet.dk

WHINN (Week of Health and Innovation)

October 19–23, 2015; November 7–11, 2016 • Odense, Denmark • whinn.dk

European Telemedicine Conference

October 21–22, 2015 • Odense, Denmark • telemedicineconference.eu

Hospital + Innovation

October 21–22, 2015 • Odense, Denmark • hospitalplusinnovation.com

SCANDEFA (Scandinavian Dental Fair)

April 28–29, 2016 • Copenhagen, Denmark • scandefa.dk/en-gb

Health & Rehab Scandinavia

May 10–12, 2016 • Copenhagen, Denmark • health-rehab.dk/en

European Society for Medical Oncology Congress

October 7–11, 2016 • Copenhagen, Denmark • bit.ly/1JhmYuh

FOODPARMATECH

November 1–3, 2016 • Herning, Denmark • bit.ly/1Jhnc4M

Anti-Aging Fair

2016 • antiagingfair.com

World Conference on Lung Cancer

December 8–11, 2019 • Copenhagen, Denmark • 10times.com/wclc-copenhagen

Resources

- Danish Health and Medicines Authority, sundhedsstyrelsen.dk/en
- Ministry of Health, sum.dk/english.aspx

Dominican Republic

Market Entry

U.S. products and services enjoy favorable access to the Dominican market. The Central American Free Trade Agreement-Dominican Republic (CAFTA-DR) provides for duty-free entry of medical equipment and pharmaceutical products. To succeed in the Dominican market in the healthcare sector, it is advisable to have a local distributor that can provide after-sales and leasing services, support guarantees, and maintain inventories for parts and supplies. Exporting directly to the private hospitals can be extremely challenging since procurement practices in public hospitals dictate that all purchases must be made through a local Dominican company. Local importers and distributors usually have sales agents who distribute the products to small retailers throughout the country. Local distributors also conduct promotional activities to encourage doctors and nurses to use and recommend their products. However, U.S. exporters should seek local legal counsel prior to signing a representative agreement with a Dominican agent to ensure that their rights to terminate an agreement in the future are safeguarded.

Current Market Trends

The Dominican market for medical equipment and supplies depends on imports. This market, which is largely dominated by U.S. exporters, has maintained a consistent demand for equipment. It is expected to continue growing, due to a very competitive situation between private- and public-sector healthcare facilities for the acquisition of modern technologies in machinery and equipment. Price is the primary determining factor for the purchase of disposable such as gauze, surgical drapes, surgical catgut, and the like. However, when purchasing surgical sterilizers, ophthalmic surgery instruments, breathing appliances and gas mask, etc., quality is the deciding criterion. The public sector bases most purchasing decisions largely on price and is very often more receptive to less expensive products even if the quality might be questionable.

Statistics

Capital: Santo Domingo
Population: 10.6 million
GDP (USD): 63.9 billion (2014)
Currency: Dominican peso (DOP)
Language: Spanish

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The Dominican Republic has become a destination for preventive medicine, orthopedics, cosmetic surgical procedures, weight loss surgery, cardiology, organ transplant, oncology, eye surgery, and dental procedures. The medical community has begun to take advantage of the tourist flow, developing attractive packages for medical tourism. The leading private hospitals are certified by the Ministry of Health, which holds international recognition, and several are either accredited in the process of obtaining accreditation through the Joint Commission International

Main Competitors

U.S. companies have 65 percent of the Dominican import market for medical equipment and supplies. There is extensive local production of surgical instruments and supplies. However, 95 percent of this production is exported through the Free Trade Zone (FTZ) Program. Products manufactured in these FTZs include; wound management products (wadding, gauze, and bandages), general surgery and minimally invasive surgery Instruments, ophthalmic surgery instruments, disposables (syringes, needles, catheters, surgical gloves, clothing for operating rooms, and surgery sponges). There is limited manufacture of surgical supplies beyond the FTZs and this production is not sophisticated, mainly involving textile products (gauzes, bandages, and surgical drapes).

Current Demand

Surgical Instruments and Disposable Supplies


Public hospitals and private clinics are by far the largest potential users of surgical instruments and supplies. For disposable surgical products such as gauze, adhesive dressings, sterile surgical catgut, sterile suture materials and sterile tissue adhesives for surgical wound closure, the primary purchaser and user is the Dominican government. For more technologically advanced surgical products, such as sterilizers, the most important purchasers are the private clinics.

Home Medical Care

The incidence of respiratory difficulties and diabetes, the aging of the Dominican population, and the CAFTA-DR free trade agreement are the primary factors behind the industry's 10 percent growth over the next three years. The market for these products is almost entirely supplied by imports and U.S. products enjoy a positive receptivity (65 percent of the market).

Used/Refurbished Medical Equipment

The Dominican market offers opportunities to exporters of used and refurbished medical equipment, especially that which has been refurbished by the manufacturer, who can use original replacement parts and provide a limited guarantee. In addition, buyers of used equipment usually require assurances that parts and maintenance can be obtained locally. Therefore, U.S. companies interested in this market should appoint a local distributor. The



market for used devices (not refurbished) is limited to hospital furniture such as operating tables and hospital beds. There are good opportunities for these products, which do not always need to be refurbished and will generally be accepted with minor defects such as scratches and tears. The Dominican government does not impose restrictions on the importation of used/refurbished medical equipment. All imports of both new and used equipment are treated equally.

Diagnostic Equipment

Tomography equipment represents a very large percentage (approximately 69.1 percent) of the imports for diagnosis and imagery medical equipment, along with the corresponding supplies and spare parts.

Registration Process

Product registration in the Dominican Republic is an arduous exercise, and has to be requested by the local office of the foreign company, or its agent distributor. The registration takes approximately “90 days” to be completed after request.

Barriers

There are no significant trade barriers. Registration of healthcare products is only required for drugs and medical devices. The Department of Drugs and Pharmacies (Departamento de Drogas y Farmacias) is responsible for issuing sanitary registration certificates.

Resources

- Departamento de Drogas y Farmacias (Department of Drugs and Pharmacies), drogasyfarmacias.gov.do

Egypt

Summary

Egyptian Medical Equipment Market, 2013–16				
(USD Millions)	2013	2014	2015 (proj.)	2016 (proj.)
Total Market Size	926	930	934	938
Total Local Production	42	46	46	46
Total Exports	17	17	17	14
Total Imports	390.5	650	868	860
Imports from the U.S.	46	50	52	48

Source: Unofficial estimates.

The healthcare sector in Egypt, although large compared to its Middle East counterparts, has been relatively stagnant over the past few years. That being said, there are a variety of investment opportunities as the Egyptian government is very keen on expanding the healthcare industry, especially relating to medical devices, and plans for the development of 26 new hospitals. Healthcare expenditures range from 3–5 percent of GDP. Currently, the Egyptian government launched Insurance coverage for all qualified Egyptians as a pilot project in seven governorates in Upper Egypt. This is the first step to be taken toward this National project. This project includes the upgrade of number of hospitals and clinics to be able to provide adequate medical service level to Egyptians.

Consumer healthcare grew by 14 percent in 2014 and spending was USD 23.4 billion. The World Bank estimates that the average life expectancy for Egyptians has increased from 69–73 from the years 2005–10. The Ministry of Health operates 1300 hospitals or 60 percent of hospital beds. Universities, the Army and the private sector constitute the other 40 percent.

Statistics

Capital: Cairo
Population: 89.5 million
GDP (USD): 286.5 billion (2014)
Currency: Egyptian Pound (EGP)
Language: Arabic

Contact

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Market Entry

The steady growth despite the economic downturn is a strong indicator of increased demand. Furthermore, 32 percent of the Egyptian population is under 14, suggesting a need for investment in the healthcare industry. Recent reports indicate that the Egyptian government prefers investing in preventative medicine, which is a specialty that caters to medical devices. According to the World Bank, less than 5 percent of total investments are allocated toward health services. Considering the strong demand and fewer barriers to the market, the medical device sector will be ripe for substantial economic growth in the midterm.

In line with the country's reform efforts to upgrade the overall healthcare system, it is expected that there will be opportunities in the long term for U.S. companies that can offer:

- Construction, management, and rehabilitation of hospitals and rural healthcare facilities
- Emergency care (ambulatory) services
- Training programs for nurses and physicians
- Establishment of quality control of biological and laboratory centers
- Development of quality standards for hospitals, laboratories, and healthcare institutions
- Providing plans for regulator and accreditation bodies
- Training programs to include FDA-drug classification for government officials

Current Market Trends

Government pledges to improve healthcare have resulted in a recent boost in the purchase of medical devices, and similarly the proliferation of privately-owned hospitals and clinics has steeply raised the demand for high-tech medical equipment in the last 10 years. It is estimated that the market for medical devices will be worth USD 970 million by 2016, and this is almost wholly made up from imports, as Egypt produces very little medical equipment.

Main Competitors

Egypt's medical device market is the second largest in the Middle East. Sales in medical devices totaled USD 484.7 million in 2013, a five percent increase from the previous year. As Egypt produces very little medical equipment, the vast majority of the market is supplied by imports, with just one Egyptian company producing a limited range of ultrasound scanners.

Technical medical equipment such as radiography and ultrasound apparatus, vital statistic monitors, dialysis machines and laboratory microscopes are imported and distributed by a handful of companies who benefit from low import tariffs, the biggest of which, El Gomhoureya, is wholly owned by the government.

Current Demand

Private healthcare providers are limited in choice and price and often choose to personally import the equipment they need, which, according to customs laws, must be brand new and unused to be brought into the country. This can be a complicated process, yet nonetheless Egyptian physicians who travel abroad for conferences often acquire devices in this manner that are not offered by El Gomhoureya.

Formerly the Egyptian healthcare system was predominantly controlled by the government, whereas in the past 10 plus years the private sector has taken on a more active role as the standard of care in the public sector has declined. Though disposable income is generally low in Egypt, making unavoidable healthcare spending a serious expense for a majority of Egypt's citizens (estimated per capita GDP was USD 3,146 in 2014), nonetheless the majority of Egyptian patients prefer to utilize private healthcare facilities.

The Ministry of Health is currently undertaking an ambitious plan of building new hospitals and renovating and refurbishing existing medical facilities with new technologies and up-to-date equipment, especially in the rural, under-served areas. The public sector is expected to account for the majority of expenditure growth in the upcoming years due to the government's Healthcare Reform Program target of achieving universal access to healthcare. The private sector's demand for sophisticated medical equipment is also growing.

Best prospects include:

- Diagnostic imaging equipment
- Oncology and radiology equipment
- Disposables
- Surgical and medical equipment
- ICU monitoring equipment
- Laboratory and scientific equipment
- Mobile clinics

Barriers

Although the economic reformers have developed considerable momentum, red tape remains a business impediment in Egypt. Also, working directly with the government bureaucracy is time consuming and the tender announcement process is not transparent.

El Salvador

Summary

The Salvadoran health sector is composed of the public and private sector. The public sector consists of several institutions:

- Ministry of Public Health (MINSAL)
- Salvadoran Social Security Institute (ISSS)
- Salvadoran Integral Rehabilitation Institute (ISRI)
- Salvadoran Institute of Teachers Welfare (ISBM)
- Military Health Service (Comando de Sanidad Militar-COSAM)
- Solidarity Fund for Health (FOSALUD)

The private sector includes hospitals, clinics, and non-profit organizations.

The Solidarity Fund for Health (FOSALUD) was created by the Salvadoran government to increase healthcare services coverage, and support urban and rural clinics and units. The Fund entered into effect in January 1, 2005, and is funded by taxes on alcoholic beverages, tobacco products, firearms, ammunitions, and similar products. The other public entities are funded by the government, international donors, and contributions of employers and employees of the formal labor sector.

The Ministry of Health has 30 hospitals, and the Salvadoran Social Security has 11. In the private system, the two main hospitals are Hospital de Diagnostico, and Hospital de La Mujer, both located in San Salvador.

The Salvadoran population considered the healthcare systems deficient, and is constantly requesting better services. The level of poverty in the country is high, and the lack of funds is the main constraint of the government investment in the sector. In 2013, El Salvador's total health expenditure as percentage of the GDP was 6.9 percent.

Statistics

Capital: San Salvador
Population: 6.4 million
GDP (USD): 25.22 billion (est. 2014)
Currency: U.S. dollar (USD/\$)
Language: Spanish

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Market Entry

To enter the market a U.S. exporter needs to identify a local distributor or representative in the country. Selling to public institutions requires participation in public bidding processes. It is recommended that the U.S. company work closely with a local partner to have effective promotion strategies and continuous presence in the market. Also, it is recommended to have a legal representative (law firm), who can assist in preparing bid offer. The lower bid is usually granted.

In general, the Salvadoran market is price driven. However, Salvadoran hospitals and clinics prefer products with high quality, competitive price, durability, ease of maintenance, and availability of spare parts and accessories. Post-sales service is very important. Additionally, to allow operators to easily handle the equipment, operating instructions and manuals are preferable in Spanish, as well as product brochures and literature.

Current Market Trends

The public sector is the key primary purchaser of medical equipment and supplies through the Ministry of Health and the Salvadoran Social Security Institute (ISSS). Public institutions differ from private entities as they only buy new equipment. Some private hospitals occasionally acquire used or refurbished equipment.

Several medium-term public and private sector projects are currently under development.

Public Sector

- The Salvadoran Social Security Institute (ISSS) is planning the construction of a hospital in San Miguel to provide health services in the eastern part of the country. The hospital will have 160 beds, and will include five surgery rooms. ISSS authorities expect to announce a bid process by October 2015.
- The Ministry of Health is planning the construction of a hospital in the northern part of San Salvador, which will provide services to the municipalities of Apopa, Nejapa, Aguilares, Toncatepeque, Guazapa and El Paisnal. The project is still seeking funds from international organizations, such as the International Development Bank, and obtaining permits. The new hospital will have approximately 100 beds and will provide surgery, pediatric, and gynecology services. The government expects to have all documentation ready for a bid by mid-2016.

Private sector

- The main private hospital in the country, Hospital de Diagnostico, is planning the construction of a new hospital in the municipality of Nuevo Cuscatlan. The new facility will have 50 beds with the capacity to increase to 100, and will be fully equipped to provide all health services. Currently, the project is in the stage of obtaining its construction permits, which can take up to 1 year.

Main Competitors

The United States is the main trade partner for El Salvador. U.S. products are preferred for quality, training programs, competitive price, and geographic proximity, which facilitate the rapid shipment of spare parts.

The U.S. is the main exporter of medical products to El Salvador; competitor countries include Germany, Mexico, and China.

Current Demand

Best prospects include:

- Diagnostic imaging equipment
- Cardiac monitors
- X-ray equipment
- Oxygen therapy and artificial respiratory ventilators
- Ultrasonic scanning equipment
- Magnetic resonance imaging apparatus
- Beds and lamps
- Disposable products

Registration Process

Medical devices, pharmaceuticals, medicines, vitamins, nutritional supplements, dental products, and natural products are regulated under the Medicine Law that entered into force in April 2012. Products need to be registered at the National Medicine Directorate (DNM, medicamentos.gob.sv). The registration requirements are available at the DNM's website.

In addition, ionizing radiation devices or equipment need import permit from the Ionizing Radiation Advisor and Regulatory Unit (UNRA) at the Ministry of Health.

Barriers

The importation of medical equipment is not restricted, and no tariffs are applied except for the 13 percent value added tax.

Resources

- El Salvador government procurement, comprasal.gob.sv



European Union

Summary

As the European Union (EU) does not have a Food and Drug Administration (FDA), the task of harmonizing requirements and regulating medical devices is handled by the European Commission in close cooperation with Member States' Health Authorities. The purpose of the EU harmonization effort is to merge the differing national requirements into one law which will be applied throughout the European Union. Legislation adopted through this process covers implantable, non-implantable and in vitro diagnostics medical devices in three separate directives that provide manufacturers the basics to certify their compliance with EU-wide safety requirements.

Adopted Legislation

The following EU directives are in force throughout the European Union consisting of 28 Member States (Austria, Belgium, Czech Republic, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, the Netherlands, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Romania, Bulgaria and the United Kingdom):


- Active implantable medical devices (90/385/EEC): Active implantable medical devices (AIMD), such as heart pacemakers or defibrillators, are defined as “any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.” Considering the potentially high risk factor of such devices for the patient, manufacturers cannot self-certify and have to rely on the services of an accredited test laboratory to complete the process of compliance.
- Medical devices (93/42/EEC): Medical devices are broadly defined as “any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper

Statistics

Capital: Brussels, Belgium
Population: 503 million
GDP (USD): 18.45 trillion
Currency: Euro (EUR/€)
Language: 24 languages

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application intended by the manufacturer to be used for human beings” for several purposes such as diagnosis, treatment, alleviation of disease and more. As the range of this directive is broad and leaves room for interpretation, the Commission has written guidance for manufacturers. Medical devices include syringes, bandages, wheelchairs, endoscopes, prescription glasses and contact lens solution, among others. As the range of devices covers minimal risk as well as higher risk devices, the classification of the product will determine whether a manufacturer can self-certify or needs to involve the services of an accredited test laboratory.

- In vitro medical devices (98/79/EC): An in vitro diagnostic device (IVD) is a “reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body solely or principally for the purpose of providing information.” It covers items such as pregnancy test kits and blood analysis machines. While manufacturers of simple IVD test kits such as for diabetes can self-certify compliance with the requirements, more high risk test kits such as HIV will require the services of a notified body.

The directives have been supplemented over time by six modifying and implementing directives. The last technical revision was Directive 2007/47/EC (bit.ly/17yl1mD), which entered into force on March 21, 2010. The main changes introduced by this directive impact medical devices and active implantable medical devices. New elements include:

- The conformity assessment procedures and classification of devices as well as the essential requirements for active implantable medical devices (AIMDs) and medical devices (MDs) have been somewhat simplified, harmonized and enhanced.
- Software with an intended medical purpose is now a medical device in its own right.
- All certificates issued by notified bodies are limited to a maximum validity of five years.
- With the emphasis on clinical data for all devices in the new directive, the European Commission published guidance on the clinical evaluation dossier in December 2009: bit.ly/H1N1bZ.
- Use of PVC softeners in certain types of devices will require labeling. Following a mandate from the European Commission for medical devices, CEN, the European standards organization, has developed a standard, EN 15986 (bit.ly/1i2aQvr), which includes a symbol to show the presence of phthalates in medical devices.
- Custom-made devices will be subject to a post-market review system.

Since directive 2007/47/EC is not easy to read, the changes have been merged with the original directives to create a single, readable text which is up-to-date.

- Directive 90/385/EEC on active implantable medical devices: bit.ly/1bFC2yJ
- Directive 93/42/EEC on medical devices: bit.ly/18t790i
- Directive 98/79/EC on in vitro diagnostics: bit.ly/1bFChK7
- Guidance document from the Commission on Interpreting Directive 2007/47/EC: bit.ly/PnzKLS

CE Marking

Known as “new approach” directives, these directives outline a set of “essential requirements,” rely on use of voluntary EU-wide harmonized standards, and offer a choice of conformity assessment modules. The distinguishing feature of new approach directives is CE marking, which is a conformity mark, affixed to the product, the instructions for use, and the packaging—indicating to inspection authorities that the product complies with the directives.

Exception to CE Marking

While CE marking is generally required on all medical devices, there are a few exceptions. All custom made implantable and non-implantable devices and devices for clinical investigations are subject to a different conformity assessment module which does not require CE marking at the end of the process. In vitro diagnostics for performance evaluation or research purposes only are not subject to the IVD directive although they may be subject to national requirements. In general, devices shown at trade fairs, exhibits, for demonstrations, etc., do not need to have CE marking. However, it is recommended to indicate clearly that non-CE marked devices are for demonstration purposes only.

Classification

Manufacturers should note that the differences in regulatory approach between the EU and the U.S. mean differences in classification and compliance verification. It would be wrong to assume that meeting the requirements for the U.S. market would satisfy the EU requirements. To illustrate this point, hospital beds including accessories, according to FDA guidance, are either Class I or II depending on the type of bed. In the EU, hospital beds and accessories are classified as Class I devices, allowing self-certification. In addition, the beds and their accessories would have to be considered separately, each as medical devices in their own right, especially when such items are sold separately.

The AIMD directive has one class and does not allow self-certification. The medical device directive covers four classes—Class I, IIa, IIb, and III. Only Class I devices can be self-certified. Manufacturers must involve a notified body in all other cases, and sterile Class I devices or those with a measuring function must also use a notified body. The IVD does not distinguish classes, but rather groups: general tests, self-testing kits, and Annex II lists A and B. For simple tests, self certification is usually an option. To help with classification if EU annexes are difficult to interpret, the Commission has published new guidance, bit.ly/PfkVYa.

Borderline Products

For the majority of medical devices, the purpose is obvious: pacemakers, endoscopes, syringes and wound dressing are clearly to be used for medical purposes. Products where the intended purpose is not so clear are known as borderline products and they may be subject to several directives. For example, a scale to weigh patients in a hospital would be subject to both the non-automatic weighing scale and the medical device directives. Disinfectants for exclusive use with a medical device may be classified as an accessory to a medical device because the intended purpose is medical rather than general. The intended purpose is usually supported by appropriate statements on the company's website or in promotional literature. It is possible to get an official interpretation to clarify borderline products but manufacturers should be able to make the determination in most cases themselves by using the guidance (meddev and IVD) provided by the Commission.

For more information, please visit bit.ly/1sda4UB.

Compliance with “Essential Requirements”

The “essential requirements” for the protection of health, safety, and environmental concerns cover risks and hazards that may occur at the design, production and handling stages. The manufacturer has to address the essential requirements which apply to a product and identify relevant risks for the patient. Non-relevant essential requirements do not have to be considered. As an example, manufacturers of arm braces made of stretch fabric would have to consider the essential requirements related to “compatibility between the materials used and biological tissues,” in other words, the fabric's potential to cause skin allergies. A non-relevant requirement for arm braces would be “protection against radiation.” Choice of packaging is an essential requirement for prepackaged devices, as damage resulting from mishandling could have an adverse impact on the device making it harmful for the patient upon use. These are just examples, bearing in mind that there are many other elements to verify and that the manufacturer should carefully review the complete list of essential requirements.

Use of EU-Wide Harmonized Standards

The task of complying with essential requirements can be simplified by voluntarily using EU-wide (EN) harmonized standards. The risk assessment management standard which facilitates the initial checking of the relevant essential requirements is ISO/EN 14971. Manufacturers may also establish their own checklists for risk assessment of medical devices.

Other than the risk assessment standard mentioned above, the Commission has listed over hundred EU-wide harmonized medical device standards addressing various essential requirements. These standards have been developed and/or identified by the European standards organizations. They are often based on international standards. References to EN standards are published in the Official Journal (the EU equivalent of the U.S. Federal Register). As a result, the standards are uniquely linked to EU legislation and are known as harmonized standards. Use of EN harmonized standards gives “presumption of conformity.” When a

manufacturer opts not to use an EN harmonized standard or prefers to design/manufacture to other standards, then the manufacturer has to show in great detail how their medical device meets the essential requirements in EU medical device legislation. All other existing standards not published in the Official Journal are either national or industry standards.

Modules of Conformity Assessment

To facilitate acceptance of the final product as meeting EU requirements, the manufacturer will have to choose a conformity assessment module as described in the annexes of EU medical device legislation. The choice of the module is determined by the classification and the preference of the manufacturer for a given module.

The conformity assessment modules address the design and production stages. For design, the manufacturer must provide the evidence of how the device meets the essential requirements. For production, the manufacturer has to put in place and document a quality system to ensure continuity in complying with the essential requirements.

Low risk products, such as Class I medical devices or self-test kits, generally allow self-certification based on conformity assessment module A which consists of establishing a Declaration of Conformity and compiling a technical file. All modules between B and H combine design and production compliance such as type examination and verification of manufacturing to type based on technical file inspection (modules B and F) or full quality assurance (module H). As these are conformity assessment modules for higher risk products, the services of an EU notified body or U.S. based subcontractor will be required to some degree depending on the classification.

Roles of a Notified Body

All active implantable medical devices and certain types of IVDs as well as medical devices belonging to Class II a or b or higher require the involvement of a notified body, the official term for accredited test laboratory based in the EU. Only notified bodies in the European Union can make the final assessment of conformity certification in accordance with EU directive(s). A U.S. based subcontractor of an EU notified body, such as UL or Intertek Testing Services, can also handle the tests for certification, but the certificate of conformity will still have to be supplied by the EU based notified body.

Technical File

The technical file contains all relevant information to support the claims of compliance with EU requirements such as a general description of the product, documentation of the quality system, design information, list of standards used, result of design calculations/inspections, test reports, performance evaluation data, sample of label and instructions for use, and Declaration of Conformity. It is to be kept either by the manufacturer or his/her authorized representative with the understanding that it should be quickly accessible upon request from an official national inspection authority.

Declaration of Conformity

Among the final steps in the CE marking process of medical devices is the drawing up of a Declaration of Conformity which consists of name and address of the manufacturer and/or authorized representative, product name, type, model number and any relevant supplementary information, the reference numbers of standards, the date, a signature with title and a statement regarding responsibility of manufacturer or authorized representative. By applying the CE marking on the product, packaging and on the instructions for use, which can be done either by the manufacturer or his importer/distributor, the manufacturer has completed the CE marking process.

Authorized Representative

Manufacturers outside the EU have to identify an EU-based authorized representative unless they have a registered company in the European Union. The primary task of the authorized representative is to be the point of contact for the national health authorities of the Member States. The representative will have to notify the national authority in the country of residence whenever a new Class I device is brought on the EU market. Some national authorities have standardized forms on their website. In addition, the authorized representative's name must be mentioned on the Declaration of Conformity.

The arrangement between the authorized representative and the manufacturer is purely administrative and subject to a commercial contract specifying the role that can be limited (authorized representative only) or broader (importer/distributor). Details about the responsibilities of manufacturers and authorized representatives can be found in the new legislative framework which covers all CE marking legislation.: bit.ly/1bFDtwX.

Other than single notification, authorized representatives or manufacturers typically also register devices in individual member states. In the future, registration will become easier. With the Commission's 2010 Decision to enforce use of (bit.ly/19eE3l2)—the EU-wide database for devices on the market—registration of in vitro diagnostics in each country became redundant. The system for medical devices, however, will remain unchanged for the time being. Exporters/authorized representatives will still have to register their devices nationally until and when the Commission decides to move to a centralized registration for manufacturers of devices. In the meantime, Eudamed will be of use to member states for internal communications and for post-market surveillance purposes. To facilitate registration, the EU encourages use of the Global Medical Device Nomenclature (GMDN) based on EN/ISO standard 15225.

Post-Market Surveillance

As the EU regulator allows manufacturers to self declare conformity, with or without involvement of an accredited test laboratory, verification of compliance to ensure safety of consumers is left to the Member States after the products have been brought on the market. As Member States each have their own system, it is possible that some countries grant extensive inspection powers to their national customs service where others may focus

their resources in local inspections. When caught in an infraction, the measures imposed on manufacturers may vary from a simple warning to a hefty fine or complete withdrawal from the market, depending on the type of infraction.

EU medical device legislation requires that Member States put in place safeguard procedures. In case of an incident involving injury or death, the Commission will be notified, thereby triggering an EU-wide rapid alert system. The Commission has been putting more emphasis on post-market surveillance, with a goal to strengthen the infrastructure of cooperation among national inspection authorities.

With the adoption of measures in September 2013, the Commission further tightened control by strengthening the criteria for the designation and supervision of notified bodies and addressing the tasks to be fulfilled by notified bodies when conducting audits and conformity assessment procedures. These measures have proven to be successful.

Coming Soon: New Regulatory Framework for Medical Devices

The existing medical device directives (MD and AIMD) are currently being reviewed following the 2008 public consultation. The purpose is to recast the regulatory framework. A proposal for a new framework was released in September 2012. The review focuses on extending the scope, introducing pre-scrutiny system for high risk devices, and improving the vigilance and post-market surveillance system.

In June 2010, the Commission launched a separate public consultation to review in vitro diagnostic device legislation. The review focuses on scope, classification and conformity assessment methods of IVDs, among others. The proposed legislation was released in September 2012 and is still undergoing review in tandem with the new proposed medical device legislation.

For more information about the review of existing legislation, please visit bit.ly/RDKx6g.

Medical Devices and Machines

Overlap with the new machinery safety directive 2006/42/EC has been clarified for medical devices that are also machinery. Only one single conformity assessment is required under medical device directives 93/42/EEC and 90/385/EEC. The risk assessment to be carried out is the risk/benefit analysis as set out in the essential requirements of the directives concerning medical devices. Harmonized standards for medical devices which are also machinery should cover in their scope any requirements of the machinery directive that are applicable to the devices. Such standards will be reviewed and amended or revised if needed.

Interpretation of the relation between the revised Directives 90/385/EEC and 93/42/EEC concerning (active implantable) medical devices and Directive 2006/42/EC on machinery, can be found at bit.ly/Od4cUM.

MRI Equipment

The revision of directive 2004/40/EC on worker exposure to electromagnetic fields was finalized in June 2013 with the adoption of Directive 2013/35/EU. The directive sets exposure limits for workers but allows a derogation for MRI. Stakeholders affected by this directive successfully lobbied the EU and Member States in order to obtain an exemption for MRI equipment. A practical guide covering procedures for hospital workers exposed to electromagnetic fields will be developed. In the meantime, the Commission published its scientific findings about EF in 2015.

Packaging/Labeling

The amended EU directive on units of measurement (the “metrics” directive 80/181/EC) entered into force on January 1, 2010, which means products must bear metric units of measurement. Use of supplementary units, such as U.S. customary inch-pound, are also allowed.

Specific requirements for labels are included in medical device directives. As for choice of language on labels, EU medical device legislation defers to Members States. For more information, please visit bit.ly/19RpuAQ or contact your local U.S. Commercial Service office.

Medical Devices Using Animal By-Products

The occurrence of bovine spongiform encephalopathy (BSE) in the European Union led to stringent measures regarding traceability of tissues of animal origin for use in medical devices. Risk assessment was addressed in guidance and standardization. The Commission adopted an animal by-product regulation in 2002, repealed in 2009 by Regulation 1069/2009, which covers use of raw material of animal origin for non-food use. Medical devices are subject to specific transport and labeling requirements. The material has to be sourced from approved plants and the process has to be documented. For more information, we suggest you contact the Foreign Agricultural Service at the U.S. Mission to the European Union (usda-eu.org).

Environmental Requirements

Growing mountains of waste of electrical and electronic equipment have forced the EU to consider ways to reduce, recover and recycle packaging and appliances. Also, the use of hazardous substances has led to environmental damages; therefore certain substances such as lead or mercury have been banned. Those issues have been tackled by the Waste of Electrical and Electronic Equipment legislation (WEEE) and the Restriction of Hazardous Substances in Electrical and Electronic Equipment legislation (RoHS).

Medical devices are within the scope of the RoHS directive since 2014; for IVD the date is 22 July 2016. Other laws such as the Waste Electrical and Electronic Equipment (WEEE) directive require OEM manufacturers to dispose of products they manufacture in an environmentally responsible way once the equipment reaches end of life. Medical devices are covered by this directive but with a specific exemption today for “implanted and infected medical devices,” go.usa.gov/DfQP.

Chemical Substances and Mixtures in Medical Devices

Medical devices containing or consisting of chemical substances and mixtures are subject to specific requirements under the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH) Regulation and the Classification, Labeling and Packaging of substances and mixtures (CLP) Regulation (export.gov/europeanunion/reachclp). REACH entered into force on June 1, 2007. It changes the former legislative framework for chemicals to ensure a high level of protection of human health and the environment. REACH makes industry responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. Under REACH, the EU can also take measures to ban the use of highly dangerous substances. CLP aligns previous EU legislation on classification, labeling and packaging of chemicals to the UN GHS (Globally Harmonized System of Classification and Labeling of Chemicals).

Resources

- European Commission, bit.ly/1cCGz67
- National health authorities, bit.ly/15OLFKE

Finding/Buying Harmonized Standards

- bit.ly/19CMJ3I
- cen.eu
- ansi.org
- www.cenelec.eu

Associations

- AdvaMed, Advanced Medical Technology Association (advamed.org)
- Medtech Europe (formerly Eucomed, Medical Technology, and Edma, European Diagnostics Manufacturers Association (eucomed.org and edma-ivd.eu))
- COCIR, European Radiological, Electromedical and Healthcare IT Industry (cocir.org)

Notified Bodies/Conformity Assessment Bodies

- bit.ly/15WqqXw

Consultants/Authorized Representatives

- go.usa.gov/DfUF
- eaarmed.org

Guidance

- European Commission guidance on medical devices (bit.ly/1gRDimd)—Reflect only the views of the European Commission. Not legally binding like decisions of the European Court of Justice, and can be challenged by Member States authorities or competitors.
- CE marking (go.usa.gov/DfPm)

Finland

Summary

Overall social protection expenditure in Finland amounted to 31.3 percent of GDP (USD 84 billion) in 2013 while healthcare accounted for 9.1 percent (USD 24 billion) of GDP in Finland. Universal coverage is accessible for all citizens and permanent residents in the country, with a range of comprehensive health services delivered primarily by publicly owned and operated providers. Approximately 75 percent of services and programs within the system are funded through public expenditure.

The Ministry of Social Affairs and Health (STM) manages the preparation and implementation of Finland's social welfare and healthcare policy. Additionally, they mandate and organize programs and reforms regarding healthcare provisions. The 336 municipalities of Finland are legally obligated to provide healthcare services for their residents (i.e. primary, secondary and tertiary healthcare), as well as to collect taxes for the financing of services provided. They accomplish this through local municipal healthcare centers, or by regional healthcare districts, all containing a central hospital, of which there are twenty. These districts provide secondary care specialists, who are only available through a referral from a primary provider. The population of hospital districts varies between about 60,000 and 1,500,000 inhabitants.

Municipalities contract a small proportion of primary care to private providers; however, that proportion is expected to increase. There are about 40 private hospitals which provide approximately five percent of hospital care in Finland. Private healthcare, excluding occupational services, accounts for about six percent of total healthcare expenditure. In these districts, university hospitals in the major cities of Finland form the basis of tertiary care, and contain the most technologically advanced facilities and medical equipment in the nation. All of the levels of healthcare are funded by the municipalities, but the national government covers the cost of medical training and participates in financing by providing a general, non-earmarked, subsidy to the municipalities.

Statistics

Capital: Helsinki
Population: 5.4 million
GDP (USD): 276.3 billion (est. 2014)
Currency: Euro (EUR/€)
Language: Finnish, Swedish, others

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High quality and technically sophisticated medical equipment has market potential in Finland, especially equipment that increases efficiency and reduces occupancy rates in hospitals. The United States has a 28 percent share of the total market and accounts for 35 percent of Finland's overall health technology exports. Finland also produces high technology medical equipment. Increasing competition in the market is expected as local production expands.

Market Entry

As a member of the EU, Finland's local legislation concerning medical devices complies with EU directives. The National Supervisory Authority for Welfare and Health, Valvira (valvira.fi/en/licensing/medical_devices), monitors the compliance of medical devices with legislation and regulations, monitors the marketing of medical devices and promotes their safe use. Please visit ec.europa.eu/enterprise/index_en.htm for further information from the European Commission, Enterprise and Industry, Medical Devices.

Medical trade is duty-free within the European Union. Import duties are collected from production coming from non-EU countries. The amount of duty for medical equipment exported from the United States fluctuates according to specific product, ranging from 5–12 percent.

Current Market Trends

In Finland, the total market for medical equipment grew 11 percent to a record USD 1.094 billion in 2014 reported by the Finnish Healthcare Technology Association. The operating costs of Finnish hospitals have been reduced, and major hospital procurement is mainly replacing older equipment and buying some new. Investments in new medical equipment within the private health care sector are expected to continue to increase.

In 2014 Finnish exports in medical technologies grew 8.3 percent to a new record of USD 2.4 billion. Exports continued to grow faster than imports. Health technology is now Finland's largest tech sector representing nearly half of all hi-tech exports and have increased at an average annual rate of nine percent for the last two decades.

Medical equipment is Finland's fastest-growing hi-tech exports. In 2014, exports of medical equipment including medical electronics and x-ray equipment for both hospitals and dental offices grew to over 10 percent to USD 1.73 billion.

Finnish hospitals are very eager to try out new technology in the implementation of most modern treatment methods. Implementation of new technologies is effective, as Finnish medical personnel are very technology literate. Local distributors provide the market with equipment packages and maintenance programs.

Finland is very advanced in its use of IT systems within the healthcare industry, relative to other European nations. According to the European Commission, Finland ranks fifth in terms

of the deployment of Health IT within the EU. Individuals within the healthcare system have widespread, simple access to convenient ePrescription and eArchive services via KanTa (personal patient portal). The use of electronic patient records among the primary health centers and secondary care hospital districts is at 100 percent.

Main Competitors

Local production for medical equipment is well known for its quality and high technology. It is concentrated in specialized sectors, such as dental equipment and specialized x-ray and IVD equipment. About 90 percent of local production is exported because of the small domestic market size. It is important to note that internationally Finnish products have garnered attention as being particularly user friendly.

Over 80 percent of the medical equipment imported to Finland comes either from or through the European Union. Direct imports from the United States account for 8 percent. Other important supplier countries are Germany, the United Kingdom, Australia, Japan, and China.

Current Demand

High-quality and technically-sophisticated medical equipment has the best market potential in Finland, especially equipment that increases efficiency and reduces occupancy rates in hospitals. Products with the best sales potential in Finland include:

- Patient monitoring systems
- Minimally-invasive surgery (MIS)
- Day surgery equipment
- Magnetic resonance imaging (MRI) equipment
- Video endoscopes
- Digital image processing
- Picture archiving

In 2012, large electromedical and X-ray equipment were in particular demand. In other segments, strong growth was also seen in smaller medical furniture and medical implants. Additionally, In-Vitro Diagnostics was considered a contributor to market growth.

The Finnish government has recognized that there is a need for a more stable synergy in regards to Health IT communications and EPR sharing between municipalities, regional districts, and private care providers. Finland has long been a Health IT forerunner with a history of user satisfaction and ease of accessibility to information. The country is continually developing and improving its nationwide electronic archive of patients' health information (KanTa), and health-related services, such as the Electronic Prescription program. In addition, innovative and ambitious projects are in the works at the municipal, regional, and national levels, all of which are viable entry points for U.S. products and services.

Registration Process

Manufacturers must include contact details and information on the products they manufacture. The National Supervisory Authority of Welfare and Health maintains a registry

for manufacturers who place medical devices on the market in their own name; assemble systems and procedure packs to form medical devices for the purpose of placing these on the market in their own name; and sterilize systems, procedure packs, or medical devices bearing CE marking.

Representatives established in Finland must submit the same details.

Extra notification is necessary if the medical product is high-risk and includes IVDs intended for self-testing and if the device contains substance of human origin.

To submit the notification, the party must be:

- Entitled to represent the company
- Authorized manufacturer's representative
- Or responsible for placing the product on the market

Notification of the cases mentioned above must be submitted within two weeks before placement on the market. This time limit applies also to the start of importing of self-testing devices.

Barriers

There are no restrictions on imports in Finland, as long as they comply with EU qualifications. Although marketing requires thorough knowledge of end user needs, the import climate is receptive to equipment that is new and of good quality. There is keen competition in the market, however.

Trade Events

Finnish Dental Congress and Exhibition

November 19–21, 2015 • Helsinki, Finland • bit.ly/18607xL

Finland's leading event for dentistry professionals.

The Finnish Medical Convention and Exhibition

January 13–15, 2016 • Helsinki, Finland • bit.ly/18s8zrY

Finland's largest medical exhibition.

Nordic Health Technology & eHealth Forum

January 13–15, 2016 • Helsinki, Finland

Available Market Research

- Dental Industry Overview
- Medical Industry Overview
- Health Technology Trade and Telemedicine

France

Summary

French Medical Equipment Market, 2013–16			
(USD Billions)	2014	2015 (proj.)	2016 (proj.)
Total Market Size	7.114	7.327	7.546
Total Local Production	5.901	6.078	6.260
Total Exports	2.500	2.575	2.652
Total Imports	3.713	3.824	3.938
Imports from the U.S.	1.225	1.262	1.300

Source: Unofficial estimates from trade association and industry contacts

Total market demand in France for medical equipment was estimated at USD 7.327 billion in 2015, with imports accounting for USD 3.824 billion. Imports from the United States were forecast at USD 1.262 billion, or 30 percent of total imports. This percentage is expected to remain approximately the same over the next three years, with overall demand growing at three percent annually.

France ranks among the top five largest medical device markets in the world. France spends three percent of total health expenditure on medical equipment and supplies and 0.3 percent of GDP, which is average for a West European country. The overall market is generally well developed, however certain subsectors in the more innovative forms of technology still present opportunities for entry. While the public sector is the largest purchaser of diagnostic, therapeutic and surgical equipment, the private sector is also a very dynamic player.

The continuing deficit of the national health insurance funds has prompted new measures to control spending on medical devices, similar to those already in force for pharmaceuticals.

Statistics

Capital: Paris
Population: 67 million (2014)
GDP (USD): 2.27 trillion (2014)
Currency: Euro (EUR/€)
Language: French

Contact

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Market Entry

To export medical devices to France, a foreign producer should have an agent/distributor. Medical devices in the French market, whether for imported products or domestically-manufactured lines, must have obtained the CE mark and must have enclosed directions in French.

Current Market Trends

The medical market is likely to only to see moderate growth, rising from USD 7.327 billion in 2015 to USD 8.557 billion by 2020. The medical manufacturing industry has seen an entry of foreign companies; larger manufacturers are now subsidiaries of multinational groups. With flagging domestic production in several sectors the French medical device market is increasingly reliant upon imports, which now account for around 50 percent of consumption.

Main Competitors

U.S. companies can expect to face competition in this market from major global suppliers such as Siemens, Fresenius, Hitachi, Toshiba, Philips, and Smith & Nephew, as well as from French players such as Air Liquide, Askle Santé, Coloplast, Landanger, Mediprema, Moria, Paul Hartmann, Peters Surgical, Proteor, Systam, and Thuasne. France is home to many subsidiaries of U.S. companies such as Abbott Vascular, Alcon, BD, Boston Scientific, 3M Santé, Baxter, Edwards Lifesciences, GE Medical, Johnson & Johnson Ethicon, Medtronic, Boston Scientific, St. Jude Medical, and Zimmer.

Current Demand

Diagnostic Equipment

Represents 35 percent of the total medical equipment market. State-of-the-art diagnostic medical imaging systems are in great demand. Applications for this technology already exist for pediatrics, cardio-vascular care, digestion, urology, and spinal/nerve treatment. As it is well accepted and effective, the demand for this type of technology will continue to grow. Health care professionals are very optimistic about a feature of medical imagery equipment known as “image networking.” This will dramatically improve diagnostics by providing an image data bank that would enable a specialist to compare the image of a current case to hundreds of previous cases.

Rehabilitation

Represents 26 percent of the total medical equipment market. It includes all types of disposable medical products. The increasing elderly population reinforces the demand for all kinds of disposable equipment and supplies such as incontinence products and care kits used by nurses and families for home-care.

Surgery

Surgery instruments and supplies represent approximately 17 percent of the total sector. Recent developments in the non-invasive surgery field could have a strong impact on everyday hospital practice. These latest advances offer superior results and also present a significantly reduced risk to patients.

Technical Aids

Medical prosthesis represents 8 percent of the total medical equipment market. Characterized by a strong potential for innovative internal prosthesis such as knees, hips, ligaments, and elbows, and with a slightly decreasing market for external prosthesis. Technological evolution, especially in the field of anesthesia, offers the potential for rapid changes in this market.

Intensive Care

Intensive care equipment such as respiratory monitoring, pumps and incubators represents about 8 percent of the total medical equipment market. Intensive care equipment includes the latest technological advances. Both public and private hospitals show a rising demand for intensive care equipment and supplies.

Hygiene

Represents approximately 6 percent of the total medical equipment sector. Patient and medical personnel safety is of growing concern to both members of the medical profession and the public. Best sales prospects will certainly focus around assuring stringent personnel safety requirements. This is especially due to the concern regarding AIDS and other contagious diseases. In the future, prevention should receive similar emphasis considering the present focus on protection.

Registration Process

All medical device sold in France have to carry the CE Mark. Registering with the French Ministry of Health is to be addressed on a case by case basis. In the very best interest of any U.S. exporter, and in the vast majority of cases, this task is handled by the importer / distributor. Indeed, a previous experience of successful registration of products with the French Ministry of Health will be a critical factor of success in order to facilitate access to end users in France.

Trade Events

Les SALONS de la SANTE et de l'AUTONOMIE

May 24–26, 2016 • Paris, France • salons-sante-autonomie.com

Annual hospital and medical equipment exhibition. Largest medical trade show in France.

Germany

Summary

Medical technology is set to remain a German domain, at least until 2020. Germany has a long history of producing high quality medical equipment, with a particular emphasis on diagnostic imaging, dental products, and optical technologies. Not only is Germany the third largest market in the world after the United States and Japan, but also by far the largest European market—twice the size of the French market, and three times as large as those of Italy, the United Kingdom, and Spain.

Germany has a strong healthcare system in terms of infrastructure, hospital beds, and trained staff. It counts 500,671 beds in 1,996 hospitals (around 596 public hospitals; 706 non-profit, and 694 private hospitals), 2,000 medical supply stores, 1,187 rehabilitation centers, 21,062 pharmacies, and 150,000 doctors' offices. The well-established infrastructure makes the healthcare industry the largest employer in Germany with currently 6.2 million employees. Another four million jobs depend on the healthcare sector. Therefore, one out of five jobs in Germany is linked to the healthcare sector.

Accordingly, German healthcare expenditures are comparatively high but also increasingly cost-contained. In 2013 total expenditures increased 4 percent to EUR 314.9 billion, roughly 11.2 percent of GDP. In per capita terms, expenditure is estimated at EUR 3,910, ranking thirteen-highest in the world, exceeded only by e.g. Denmark, the United States, Switzerland, Denmark and Norway.

Approximately 76.8 percent of healthcare spending is sourced from the public sector, mostly the statutory health insurances. As public health insurance funds continue to record deficits of averaging EUR 3.3 billion and public hospitals are operating at a loss, health reforms and cost-cutting measures keep the market tight and increase pressure on prices. Hospitals in the public sector are therefore pressed to maintain existing equipment rather than investing in new units. Private hospitals, now at 30 percent of hospital total in Germany, as well as the 60+

Statistics

Capital: Berlin
Population: 83.8 million (2013)
GDP (USD): 3.4 trillion (2013)
Currency: Euro (EUR/€)
Language: German

Contact

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university hospitals with specialized departments, seek price-competitive state-of-the-art technologies and equipment offering proven cost savings/.

The German healthcare industry offers high growth potential and provides opportunities for U.S. medical technology exports. The Federal Ministry of Economics anticipates that by 2030, an additional two million people will be employed in the industry. Current austerity measures are likely to hit the pharmaceutical industry harder than the medical device industry, which continues to be a job engine and is expected to achieve steady growth over the next five years with annual growth rates of 3–4 percent. In 2012 over 51 percent of German healthcare technology manufacturers reported to have created new jobs, with a very positive outlook.

According to the German Advanced Medical Technology Association (BVMed), the medical devices industry employed 195,000, with a market valued at EUR 25.19 billion in 2014. The German market accounts for 40 percent of the entire EU market for medical devices.

For general statistical information published by the German Federal Statistics Office, please visit destatis.de/EN.

Market Entry

Distribution Practices

Most medical equipment imported into Germany is either sold direct through a local subsidiary with a field sales force, through medical distributors with an established distribution network, or through appointed agents or manufacturer representatives. Local representation or market presence is essential when considering differing standards and certifications, warehousing costs, maintenance, accessibility, and local marketing/sales preferences/discussions. An agency agreement is often a cost effective mechanism to enter the market but under German law—even if the agent's performance is not satisfactory—it can be difficult and costly to terminate the arrangement, particularly under an exclusive arrangement. A representation or distributorship agreement may be harder to arrange but the German associate will, in fact, purchase the product which is to be sold, thus sharing the marketing risk. Finding a mid-size distributor covering all of the German, or German-speaking, market has become harder since large manufacturers have increasingly purchased the good distributors off the market to gain access to established distribution channels, rather than developing those themselves. Thus, GE Healthcare bought Medicalis and Idel, and Donjoy bought Ormed, amongst others. As Germany's healthcare market is very decentralized and regional, it may therefore be a viable alternative to seek regionally active and well-established dealers/distributors for northern, southern and eastern Germany with defined territories.

In addition to complying with standards and regulations, U.S. companies should seek to meet some additional criteria to assure product acceptance recognition and marketability when trying to enter the German market. For example, they should supply product information and technical data sheets in German. At a minimum, catalog inserts should be in German.

Companies should also provide operation and instruction manuals in German to insure proper understanding and usage of equipment, as well as providing reliable after-sales servicing and product support or select qualified agents or distributors who are capable of providing quality service. U.S. companies should maintain close contact and good feedback with agents and dealer/distributors in Germany in order to stay informed about market developments, trade issues, regulations, and laws concerning their products.

Product Standards

The German market for medical devices is regulated by German and European Union (EU) directives, standards, and safety regulations. The requirements are complex and based on environmental, consumer health, safety and social concerns. Not all standards and regulations are mandatory, but compliance greatly enhances a product's marketability. Advice on the requirements and compliance certification in the case of a specific product should be sought from the sources referenced below.

The German Medical Products Law (MPG) of 1995 underwent a revision in July 2014. It applies to all equipment, instruments, devices, and materials, which are used on or in the human body and is relevant when trying to get permission to enter the German market. Exceptions are those devices, which achieve their intended effect pharmacologically. About 400,000 different medical products fall under this legislation. The MPG implements EU guidelines covering medical and diagnostic products. Devices complying with the MPG or its equivalent directives in other EU countries must carry the CE mark. They have the advantage of being permitted on the market anywhere in the EU without further certification requirements.

The German Federal Parliament adopted the VSG-Medtech Benefit Assessment to Strengthen Care Provisions in the Statutory Health Insurance System, in mid-June 2015. Taking effect August 1, the Act will introduce a number of new provisions for the outpatient and inpatient segments. Patients will be entitled, for instance, to obtain a second opinion and hospitals will become more involved in the provision of outpatient care if the outpatient segment is unable to arrange consultant appointments with specialists in due time. Also, an innovation fund with EUR 300 million will be established to improve cross-sectoral care. Hospital discharge management will also undergo reform. Important for medical device suppliers is the planned rule on benefit assessment for new methods and medical technologies. Innovation steps will not be subject to review by the Federal Joint Committee. Procedures based on a new scientific concept and particularly invasive methods of class IIb and III will be included for review. This will be further specified in an ordinance.

Packaging and Labeling

The European Union does not set packaging and labeling requirements in general, only in very specific high-risk product related cases. In the absence of any EU-wide rules, the exporter has to consult national rules or inquire about voluntary agreements among forwarders, which affect packaging and labeling of containers and outer packaging. The importer or freight

forwarder is the first point of contact for shipping documents and outer packaging/labeling. EU customs legislation only regulates administrative procedures, such as type of certificate and the mention of rule of origin on the customs forms and shipping documents.

Product specific packaging and labeling requirements applicable throughout the EU apply to food, medicines, chemicals, pharmaceuticals, and other high-risk items. The purpose of harmonizing such legislation throughout the EU is to minimize the consumer risk

Payment and Financing Practices

In Germany, the period allowed for payment is between 30 and 60 days. Early payments are credited with a 3 percent discount, and supplier credits in form of LoCs are common.

Practices regarding financing, availability of capital, and payment schedules are comparable to those in the United States. There are no restrictions or barriers on the movement of capital, foreign exchange earnings, or dividends. Virtually all major U.S. banks are represented in the German market, principally (but not exclusively) in the city of Frankfurt/Main, Germany's financial hub. Similarly, a large number of German banks, including some of the partially state-owned regional banks, maintain subsidiaries, branches and/or branch offices in the United States. Germany is not eligible for support from OPIC, TDA or similar agencies.

Tariffs and Import Regulation

There is no import duty on medical devices; only a 19 percent import turnover tax payable at the port entry. For customs clearance, a product description is required describing the use, origin and value of the product. The cost of the import-turnover tax is usually offset by ultimately passing it on to the end-user in later distribution stages in the form of a Value-Added Tax (VAT), known in Germany as Mehrwertsteuer (MwSt).

Current Market Trends

The current German government has proposed several new health plans to improve and ensure the quality of hospitals, doctor offices and provide the best healthcare to patients of any age group. As of January 2015, it is mandatory for each insured to have an electronic health card which stores personal patient data. The new Care Provision Strengthening Act (Versorgungsstärkungsgesetz) creates incentives for doctors to open their offices in rural areas due to a demographic aging among medical staff and resulting shutdowns of GP offices. In addition, the Hospital Structuring Act (Krankenhausstrukturgesetz) stipulates quality standards for hospitals and their review and screening. Large scale cost savings and further hospital efficiencies and consolidation are expected as a result. As of today, many hospitals still face the possibility of insolvency.

An e-health initiative started in 2010 and is expected to be transposed into an e-health law in 2016. Its goal is to promote pilot projects and create incentives to set up the necessary

infrastructure for telemedicine. Furthermore, digitalization investments for hospitals will continue to receive funding support from the federal government.

Main Competitors

The German market for medical devices is sophisticated and well served. Germany has a handful of large producers, headed by Siemens, B. Braun and Fresenius. 95 percent of the German medical technology industry is characterized by small and mid-sized companies or sub-groups of larger companies. Almost 1,200 SME companies (more than 20 employees) employ over 125,000 people and 11,300 smaller companies employ around 75,000 people. 95 percent of all companies employ less than 250 employees and rarely does one company represent more than 2 percent of the entire sector. In addition, foreign industry giants such as Philips (NL), Hitachi (Japan) and Toshiba (Japan) are well entrenched. GE Medical, Medtronic, Agilent, 3M Healthcare, Hollister, Johnson & Johnson, and Medline are only a few of the many German subsidiaries of U.S. medical device suppliers.

As a result of a low-growth domestic market, the German medical technology industry has to rely heavily on export markets for continued growth. On average, German medical technology companies export between 60 percent and 65 percent of their products. In 2014 foreign sales rose by 2 percent and the exports reached 68 percent of local production. Around one-fifth of these exports went to the United States. Next to a strong German manufacturing base, imports supply around three-quarters of the German medical market (USD 16.7 billion). Between 2007 and 2011 medical device imports recorded a CAGR of 6.6 percent in Euro terms and 7.0 percent in USD terms. U.S. medical device exporters to Germany continue to hold a 27–30 percent import market share, depending on product. U.S. suppliers of innovative and price-competitive products especially can compete strongly on the German market.

Current Demand

There is a stable demand for high-quality advanced diagnostic and therapeutic equipment, innovative technologies and minimally invasive equipment, in vascular surgery, urology, gastroenterology, dermatology, and neuro-surgery. Major trends are wearable and wireless medical technologies. At the same time, the demand for specialized software to protect wireless medical devices and healthcare systems against cybercrime and malware is expected to increase. Furthermore, the German medical market experiences a clear trend towards personalized medicine based on individual patient requirements. This reflects on medical packaging with increased demand for flexible and compact packaging machines.

The trend is toward miniaturization of electro-medical equipment and nanotechnology products. New technologies in emergency and first responder care along with computer-assisted surgery are widely discussed among the German medical community. Germany is also proactive in coming up with solutions to address the aging population. Therefore, there will be an uptake in demand for diagnostic equipment to detect chronic diseases in their early stages

in order to prevent higher costs. It will also spur the demand for specialized wound care and easy-to-use home care products for diabetes, orthopedic appliances, and dialysis equipment. Third, big data technology is in high demand in all segments and in the context of evaluating data for new therapies and cost-containment measures as well as healthcare prevention.

Registration Process

In 2013 the EU Commission was considering a fundamental revision of the regulatory framework for medical devices, including a central premarket authorization (PMA) system for implantable devices, and randomized clinical trials. On September 09, 2013, the EU Parliament took vote on the draft regulation and rejected it. Representatives of German industry and government were concerned that the comparative advantage of European medical manufacturers would be lost, and investment would decrease, if the new rules were to be approved. With the new EU commission, appointed in November 2014, it is expected that the next revision will take place after 2018/2019.

The CE Mark signifies that a product fulfills all necessary EU requirements. CE marking is a legal requirement for a wide range of equipment manufacturers in Germany. Certification requirements for use of the CE mark vary depending on the product. For some, such as those in the MPG low risk class I, the manufacturers (or importer/ authorized representative, if the product is manufactured outside the EU) may self-certify compliance with EU requirements and affix the mark; for others the certification of a “notified body” (an accredited certification agency such as the TUEV) will be required. For the medical aids sector, the workability and safety of a product is now considered satisfied by CE marking. The CE mark is a visible indication that the manufacturer signed a “Declaration of Conformity” prior to affixing the CE mark, claiming compliance with all relevant CE marking directives in force.

All electro-medical equipment in Germany must be suitable for use with 220 Volt, 50 cycle electrical current, and should have VDE or TUEV approval. A UL approval is not a substitute but is helpful to obtain “GS/VDE,” or GS/TUEV” approval in Germany. “GS” stands for “geprüfte Sicherheit” (safety tested). Although “GS” and the “VDE” (or “GS and TUV”) marks are not required by law, they are highly recommended for marketing electro-medical goods in Germany. These labels denote high product safety; German consumers look for these labels as Americans do for the “UL” mark.

The U.S. Product Safety Testing Institute, Underwriters Laboratories (UL), the VDE Testing and Certification Institute, and the TUEV Product Service, have formed a strategic alliance for testing of electromagnetic compatibility (EMC) which has resulted in globally recognized EMC test mark. For manufacturers of electrical and electronic products, this cooperation has led to a substantive simplification of EMC testing. Through a single test carried out by one of these three partners, a product can now be awarded an international EMC mark, which replaces the national test marks in the major world markets of Europe, the USA and Japan.

Barriers

Companies exporting medical devices to Germany will not encounter any direct trade barriers or quotas. Non-tariff, indirect trade barriers could include the complex German reimbursement system, the need for additional registration procedures in the case of medical assistive technologies, for example, or products sold in pharmacies, with the requirement to apply for HMV or PZN codes, respectively. For Class 2 medical products, the German medical products law requires manufacturing and distribution control/quality control documentation.

Trade Events

BIOTECHNICA

October 6–8, 2015 • Hanover, Germany • biotechnica.de

Europe's leading trade fair for biotechnology, life sciences, and laboratory equipment. More than 600 exhibitors.

REHACARE

October 14–17, 2015; September 28–October 1, 2016 • Düsseldorf, Germany • rehacare.de

Europe's premier rehabilitation and care event; open to the public. 50,000 visitors and 805 exhibitors from 32 countries.

A+A 2015 (Safety + Health at the Workplace)

October 27–30, 2015 • Düsseldorf, Germany • aplusa-online.de

The world's largest and most important specialist trade fair for all aspects of safety and security. Includes safety, security, and health management, including prevention and therapy of work-related illnesses. More than 55,000 visitors and more than 1,600 exhibitors.

BIO-Europe

November 2–4, 2015; November 7–9, 2016 • Paris, France • ebdgroup.com/bes

Europe's largest biotechnology partnering conference. Nearly to 3,000 global decision makers from biotechnology, pharmacology, and finance attend annually.

MEDICA with Compamed

November 16–19, 2015 • Düsseldorf, Germany • medica.de • compamed-tradefair.com

Considered the world's most important and largest international fair for medical equipment. Medica attracts 147,000 trade visitors from more than 70 countries and over 4,500 exhibitors from 80 countries. Compamed, the marketplace for suppliers to the medical manufacturing industry, attracts 600 exhibitors from 40 countries.

FIBO 2016

April 7–10, 2016 • Cologne, Germany • fibo.de

The world's leading trade show for fitness, wellness, and health. More than 80,000 visitors from 100 countries and more than 650 exhibitors from 38 countries.

OTWorld

May 3–6, 2016 • Leipzig, Germany • ot-leipzig.de

Innovative technology, new products, and high-quality professional training. The orthopedic and rehabilitation industry's leading event worldwide. More than 19,500 international visitors and 537 exhibitors.

IDS (International Dental Show)

March 21–25, 2017 • Cologne, Germany • english.ids-cologne.de

The world's leading trade show for the dental industry including dental practices, dental labs, the specialist dental trade. More than 125,000 visitors from 150 countries; more than 2,000 exhibitors from 56 countries.

Available Market Research

- Biotechnology
- BVMED Annual Report (2014–15)
- Ernst & Young Medical and Biotech Reports
- Evaluate Medical and Pharma Reports
- Accenture Hospital Report
- Business Monitor Reports
- Customized Market Analysis

Greece

Summary

Amidst the six year of recession, a newly-elected government and negotiations for economic settlement with EU creditors, Greece's geographic location continues to make the country a business gateway into Southeastern Europe. Once Greece reaches settlement and the country returns to economic stability, the government of Greece plans to implement its strategy which claims to grant Greek citizens equal access to the public health system.

The newly-elected Greek Prime Minister announced the government's top priorities in the health sector:

- Upgrade in public hospital staffing via the recruitment of 4,500 qualified staff of doctors, nurses and paramedical disciplines to cover all the gaps that exist across the country.
- The immediate operation of Intensive Care Units.
- The free access of all citizens to health services and health care, whether insured or uninsured.
- The immediate implementation of the national electronic health records which is an EU member-state obligation.
- The support and growth of health centers and hospitals in the more distant island and mountain regions, such as the Aegean Islands, Thrace, Western Macedonia and Thesprotia.

One of the prime characteristics of the Greek healthcare market, inclusive of medical device and diagnostics, supplies, and pharmaceuticals, is its high level of imports. As the current environment is impacted by the political and economic situation, and thus difficult to evaluate recent data and prospects, it is important to take into account the recent history and trends. In particular, spending in 2011 of EUR 21.80 billion(USD 30.31 billion) was reduced to EUR 20.34 billion USD

Statistics

Capital: Athens
Population: 11.1 million (est. 2015)
GDP (USD): 241.8 billion (2013)
Currency: Euro (EUR/€)
Language: Greek

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25.83 billion) in 2012 in both the public and private healthcare sectors. The government is finalizing the merger of many hospital units and attempting a twenty-four hour operation standard within all public hospitals, with a greater level of transparency in hospital financial transactions and hospital procurement. Healthcare expenditures as a share of Gross Domestic Product (GDP) in Greece have been reduced to 6.3 percent annually in 2012. This expenditure is comprised of approximately 60 percent government-provided care and 40 percent private care. Preference for private healthcare has been higher in Greece than in most EU countries during the recent years, although this is changing, given the economic situation and Greek citizens' ability to pay for private care. Still, healthcare is the number one concern since more than 25 percent of the population is over 60 years old.

The Social Security Services Fund (EOPYY) provides services in all national bodies. However, its current debt amounts to EUR 1 billion, the state currently owes pharmacists over EUR 280 million. The inability of EOPYY though to pay off its suppliers severely impacts the public health system as the suppliers are not able to continue investment and importation of innovative products and technologies.

Apart from the growing debt towards pharmaceutical and medical device companies, negotiations are currently taking place regarding the sale of over-the-counter non-prescription drugs via channels other than just pharmacies (e.g. supermarkets, etc.). The expectation is that if by 2017 there is an open market, the turnover will reach 64 percent (up from the current 36 percent). This forecast stems from the European experience whereby non-prescription drugs represent 18 percent of the total pharmaceutical market while in Greece the figure is merely at 5–7 percent. The current expectation is that non-prescription drugs will be “fully liberalized” by January 2016.

Market Entry

As a member of the European Union (EU), Greece applies the EU common tariff schedule on products imported from non-EU countries. All products, regardless of origin, are subject to the value-added tax (VAT) which is 23 percent for most products and 13 percent for pharmaceuticals. A further increase is under debate, as a result of the government's intention to raise more funds to fight the budget deficit.

Medical Equipment and Devices

While duties are applied to parts of medical products and disposables, U.S. medical equipment receive duty-free treatment. Within the EU medical device legislation has been harmonized through the European Union's Medical Devices Directive 93/42/EEC. This enables a manufacturer who has approval in one EU country, to gain access to Europe's entire market without having to obtain approvals from each additional country. All low risk devices, which are in conformity with the requirements of the directive, must carry a CE mark. Higher risk classified products, in addition to the CE mark, must carry the identification number of the certifying organization that performed the conformity assessment and issued the approval.

National implementation of the Medical Device Directive requires instructions for use in the national language. However, technical manuals and promotional material may be in English, French or German. Representatives in Greece can assist U.S. companies to meet these standards, if the U.S. companies have not already done so, in an effort to enable them to gain access to EU's entire market. Other Directives they follow under the European Legislation are Data Protection Directive (95/46/EC), Electronic Signatures (1999/93/EC), Patient Rights in Cross border healthcare (2011/24/EU), Medical Device (90/385/EEC), (93/42/EEC), (98/79/EC), Electronic Commerce (2000/31/EC).

The medical devices and diagnostics total market value for 2012 was EUR 1.2 million whereas sector experienced a decrease of reduction of 10 percent during the period 2013–14.

Over-the-Counter Medicines and Dietary Supplements

All the details pertaining to the introduction of a new food supplement to the Greek market are outlined in the Greek Government Gazette #935 of November 13, 1995 and in the EU Directive 2002/46/EC of the European Parliament. A U.S. company interested in entering the Greek market is advised to find a local agent/distributor in order to expedite procedure normally encountered during the registration approval process. The National Organization for Medicines (EOF) is the official authority for granting authorization to the sale of medicines and drugs in Greece.

In 2012, a plan to merge the National Organization for Medicines with the Hellenic Food Authority and other similar organizations was proposed to the Greek government by appointed consultants. With this merger, the new centralized agency would resemble the U.S. FDA and contribute towards a more immediate regulatory process.

Current Market Trends

Medical Equipment and Devices

The Greek market for medical equipment was estimated in 2010 to have increased by EUR 5.4 compared to the previous year. It is estimated that the Greek market for medical equipment in 2010 reached USD 1.569 billion, out of which around 95 percent was supplied by imports. The greater share of the companies' revenues is recorded in their business with the public sector (at around 80 percent) but this slightly changed due to the revised company focus toward the private healthcare sector, given its ability to pay for the products it buys in a reasonable time frame. As of 2012, approximately 13,000 individuals are employed in the Greek pharmaceutical and medical supplies fields. Medical Devices and Diagnostics total market value reached EUR 1.2 million in 2012 and faced a decline of approximately 10 percent from 2011 as a repercussion of the economic crisis. However, for 2013 onwards this decline has been stabilized from 10 percent reduction with signs of positive prospects thereafter.

Health IT

Health Information Technologies (e-Health) consists of hardware and software systems used by healthcare professionals to gather, file, classify, have access to, and electronically exchange healthcare information including administrative, clinical and other supportive systems. eHealth is one of six prioritized markets in the European Commission's Lead Market Initiative, a public-private dialogue to promote innovation and an open market. The Commission's eHealth Action Plan 2012–20 sets out the following goals and asks member states to work closely together with EU institutions to:

- Achieve wider interoperability of eHealth services.
- Support research, development and innovation in eHealth.
- Facilitate uptake and ensure wider deployment
- Promote policy dialogue and international cooperation on eHealth at global level.
- Improve legal and market conditions for developing eHealth products and services.

s stated in the European Action Plan, the development of e-Health aims to improve the implementation of digital systems for monitoring and home care for the elderly and chronically ill, in disseminating the use of telemedicine technology for diagnostic and therapeutic purposes, to enhance the safety and quality of cross-border health services, promoting innovation to create new products and services that can contribute to the sustainability and efficiency of health systems, and generally improve the quality of life of Europeans citizens. In addition, the development of e-health services can contribute decisively as a major engine of growth and competitiveness in European industry and technology.

In terms of e-Health, Greece scores below the EU 27 average regarding availability of Information and Communication Technology (ICT) infrastructure (computers and Internet) and the use of ICT for e-Health purposes. Although Greece was lagging behind the EU in internet penetration and broadband, the aim of the National Digital Strategy was to reach the EU average by 2010, and the recent government efforts through its National Digital Strategy (2007–13), including related investments of over USD 665 million have already led to considerable improvement. In particular, Greece is quickly catching up to the above-mentioned EU average (20%). According to the National Telecommunications and Post Commission, by the end of March 2012, the market grew by 8.1 percent year-on-year.

Although the use of ICT technology for use in healthcare appeared in the 1980's, ICT solutions have not yet been strongly adopted in healthcare practice in Greece. This is mainly due to the rather late development of an e-Health strategy. However, the successful Conference under the Greek Presidency [E-Health Forum 2014] shows that e-governance together with private business initiatives may change the scenery.

The eHealth Forum 2014 served as the meeting point for the six Actions Groups of the European Innovation Partnership on Active and Healthy Aging (EIP on AHA). The Forum

brought together the High Level eHealth Conference and Exhibition, the eHealth Network Meeting and many more events, and become a true forum for the exchange of experience, mutual support, good practices and innovation.

The first preparatory meeting for the eHealth and the Greek eHealth Ecosystem took place in July 20, 2013, thus reinforcing the strong commitment and investment in the deployment of eHealth solutions and the dissemination of good practices. Therefore, the required infrastructure, including standards, a national health portal, insurance smart cards, and electronic information systems will start becoming available in the upcoming years. eHealth facilitates the values of equity and solidarity by enabling the access to high quality services and safer care for all, including numerous groups of citizens with chronic diseases and the elderly. At the same time it serves as the backbone for necessary structural and functional reform and for addressing the issue of shortage of financial resources.

Greece considers that ICT solutions and eHealth as valuable and sustainable outcomes for the society. In May 2014, Greece hosted the e-Health Forum 2014, which presented the concept of "eHealth ecosystems," a true challenge for the further development of meaningful partnerships engaging the entire range of health, well-being and social care stakeholders comprising both Public and Private sector.

Regardless of the recession, Greece aims at driving eHealth forward. The Greek president has encouraged the development of visionary policies and looked into maximizing health and economic benefits and the potential for employment through new technologies.

Additionally the development of e-procurement in the healthcare sector, including electronic tender management, order management, inventory management is focused on reducing bureaucracy, cycle times, leading to overall efficiencies.

Best prospects include:

- Hospital procurement based on Electronic Data Interchange systems
- Transactional information systems
- Smart health insurance cards
- National ambulance service information systems
- Organ transplantation coordination and control information systems
- National blood-bank information system
- Primary care information system
- Medical libraries information system
- Clinical information systems—radiology, nursing, computer-assisted diagnosis, surgery training, and planning
- E-care and telemedicine (i.e. disease management, and remote monitoring)
- Mental health and wellness provider information systems
- e-Prescription and e-Referral, e-Labs systems (inclusive of provisions for appropriate accreditation, testing and certification).

Medical Tourism

Based on recent statistics, more than 10–15 percent patients from EU states seek health-care abroad. Moreover, Greece is one of the most popular tourist destinations world-wide. It has the potential and suitable infrastructure to attract patients/visitors from anywhere in the world, including Europe, and it can meet the requirements of many forms of Health Tourism compatible with its unique natural environment. Greek public and private agencies, mainly in the tourism sector (Association of Greek Tourism Enterprises, Hellenic Chamber of Hotels) strongly encourage the development of medical tourism recognizing the significance of and relevant benefits for the country, such as the extension of the tourist season. There are several contemporary hospital units found in popular Greek destinations including Crete, Peloponnese, Thessaloniki, Corfu, Alexandroupolis, Kalamata and Athens. They are pioneers in the development of domestic medical tourism, already suitably equipped to meet the needs of patient/visitors.

Over-the-Counter Medicines and Dietary Supplements

The regime for over-the-counter medicines (OTCs) and dietary supplements, including vitamins is highly restrictive. Greece is among the few EU countries that both set prices throughout the vertical production chain for OTCs (ex-factory, wholesale and retail prices) and restrict their distribution to licensed pharmacies only. The joint restriction severely limits competition in the market, leading to under-investment in the sector and poor availability of OTCs and dietary supplements for consumers. The OTC healthcare market in Greece is characterized by consolidation of global supplies, with multiple foreign brands active in the market. This market condition does not seem likely to change, as multinationals are only becoming stronger and traditional Greek companies are moving towards importing rather than manufacturing medicines. The trend of health and wellness in Greece has favored companies in nutritionals, herbal/traditional products and in OTC healthcare, for example vitamins and dietary supplements.

A recent contributor to the sector's positive growth is the ongoing trend towards self-medication as many Greek people are now avoiding a visit to the doctor for economic reasons. Also, further to the recent removal of non-prescription products from the public reimbursement plan, and their relevant transfer to official OTC status, there is opportunity for OTC market development in the future. Availability without prescription from the Greek public reimbursement scheme supports the development of a real OTC market in the longer term.

During the past couple of years, weight management in Greece encompassed a shift away from meal replacement slimming and move towards weight loss supplements and OTC. Dynamic new product launches within weight loss supplements and the positive performance of GlaxoSmithKline's example of an OTC obesity brand, were the main reasons for the shift towards weight loss supplements and OTC respectively. Weight loss supplements recorded the fastest value growth in weight management in Greece during the past couple of years, increasing in value by 13 percent.

The Greek vitamin and dietary supplement market has grown significantly during the last decade, creating investment opportunities. Consumption of vitamins and dietary supplements has increased as people learn of potential beneficial effects through advertisements and their doctors. Vitamins and dietary supplements increased in value by 2 percent in 2011 and onwards, including those which are normally associated with health and beauty and skin health as well as anti-ageing and anti-stress products and products which boost immunity and energy levels.

Particular reference was recently made by the Greek prime Minister the creation of direct and indirect incentives to increase domestic production, in order to strengthen exports.

Dietary supplements and herbal/nutritional products remain under the supervision and control of the National Drug Administration (EOF) with very few exceptions (e.g. herbal nutritional supplements). Consequently, the majority of these products can only be sold through pharmacies, are not eligible for reimbursement and their prices are set according to a reference price system. Cosmetics also fall under the supervision of the EOF following the European Regulation No. 1223/2009, which is common for 31 European countries, as well as the REACH regulation on chemicals No. 1907/2006.

Main Competitors

In the Greek market, there are approximately 300 active companies in the medical device field. These companies are mainly importers and distributors of scientific and medical equipment which also provide after-sales services. Key suppliers of medical equipment to Greece are the United States, Germany, and Italy, and to a smaller degree, the Netherlands, France, United Kingdom, and Luxemburg. The EU has acquired a major share of the Greek market due to geographic proximity, product quality, established marketing arrangements and favorable tariff treatments. Domestic manufacturing in this sector is not highly developed. Consequently, the supply capability of Greek companies is largely limited to low-value products such as syringes, bandages, gauze and various small medical devices. The medical equipment market in Greece is highly competitive because of the number of diverse importers. The structure of the public healthcare sector and especially the bureaucratic process of the existing tender system make it imperative for U.S. suppliers to have local partners. Competitive strategies focus mostly on pricing, and payment terms, particularly when dealing with the public hospitals. Leasing is also an option, especially for large, high-tech, expensive equipment. The most active and profitable subsectors for foreign suppliers include surgical equipment and supplies, electro medical equipment, IT healthcare systems and telemedicine technology. Specifically for IT healthcare, there is significant demand for products that increase the patient's safety through reduction of medical errors, while improving health information management.

Relevant U.S. company presence that can provide a vital and value adding contribution in the Greek market includes: 3M, Abbott, Alcon, Bard, Baxter, Becton Dickinson, Boston Scientific

Hellas, Carestream, Edwards Lifesciences, GE Medical Systems, Johnson & Johnson, Medtronic, Stryker, and Teleflex Medical. It should be noted that the actual share of U.S. imports was much higher than the estimated 18 percent because a large amount of the medical equipment was produced by the European subsidiaries of U.S. companies and are registered as having originated in the EU

Current Demand

There are two major sources of demand for medical devices:

- Public Health Institutions (hospitals, health centers, and regional clinics)
- Private Health Institutions (hospitals, clinics, diagnostic centers, and professionals)

Demand from consumers represents a small but increasing segment of the market. Research shows that demand for medical equipment from public hospitals represents approximately 80 percent of the total demand, making public sector hospital payment delays a serious concern. There are ongoing public and private initiatives to reduce the mismanagement of public capital and delay of payments, which the new government claims is at the top of its agenda. Additionally, the Greek government has agreed to start paying off debt to hospital suppliers and to maintain the uninterrupted flow of medical supplies and consumables to the public hospitals but this is still in process.

During the past year, progress has been made in the electronic processing of prescriptions which leads to better drug control within the public sector. Doctors are now required to electronically prescribe medication. With this change the government has started to regulate the budget for pharmaceuticals accordingly.

The challenges within the public sector have created an opportunity for the private sector to grow in importance. The involvement of the private sector in health care delivery is extensive and has been growing rapidly since the early 1990s. The current number of private hospitals is 146 with a total capacity of 38,628 beds and 140 hospitals in the public sector with 37,027 beds accounts for 95.9 percent of the total healthcare infrastructure. Most of these facilities are general and maternity hospitals. There are also 170 private clinics in the country with another 15,028 beds. (BMI, source 6) The private hospital sector accounts for 39 percent of all health services provided in Greece, trying to capture opportunities in new areas, such as medical tourism.

The market leaders in the private Healthcare Sector in Greece are the Athens Medical Group, Euromedica, Hygeia Group, and IASO Group. These medical business groups have grown tremendously from the past decade. These companies continuously seek to increase their stake in the market, however, because of the current economic situation, operate under financial pressure. Already, they have established facilities in Greece, and some neighboring countries such as Albania and Cyprus. The private health care sector is averaging an annual growth of 13–15 percent. General and diagnostic clinics have averaged 16.8 percent and 8.4 percent

annual growth, respectively. In terms of primary health care, there are more than 25,000 private practitioners and laboratories, and approximately 250 diagnostic centers in Greece, most of which are equipped with, “big ticket” medical technology. Private practices, labs and diagnostic centers are also contracted through social insurance funds to provide health care services to their beneficiaries. Remuneration is on a fee-for-service basis. Rehabilitation services and services for the elderly (geriatric homes, etc.) are predominantly offered through the private sector. Finally, the private sector through its digital strategy, together with the Ministry of Health are following an ongoing development/adaptation of Hospital Information Systems applications, to comply with the newly introduced and evolving, requirements on DRGs, billing, and reporting.

Greece’s recently-elected government encourages price reduction on drugs and medical procedures, prioritizes life-saving treatments for chronic diseases (cancer, hepatitis C, HIV, diabetes, etc.), announces focus on transparency and accountability in the public health sector (concerning pricing and reimbursement policies), and supports healthy generics competition.

Registration Process

There is no requirement for an FDA certification since it is not accepted by the EU Legal framework. Every product even if it has an FDA Certification should comply with the European standards. More particularly, companies interested in exporting to Greece should apply through the importing company to the National Organization for Medicines (EOF), indicating the country and the laboratory that produced the pharmaceutical as well as precise details about its active ingredient. The company importing the U.S. pharmaceuticals should also have a specialized license to import pharmaceuticals obtained by EOF. The exporter and/or the product should also comply and be certified with the Good Manufacturing Practice (GMP) by a member state of the EU. This can be based on the Compilation of Community Procedures on Inspections and Exchange guidelines as described in the Outline of a Procedure for Coordinating the Verification of the GMP Status of Manufacturers in Third Countries. Additional documentation, such as the license to produce the pharmaceutical product by the FDA should be provided. Finally, relevant fees will be applied for the procedure.

There are no import restrictions for medical devices. However, there is a requirement for CE Certification (European Conformity) according to the European Law which can be provided by the authorities of any EU country and is accepted by the member countries of the EU. According to the Council Directive 93/42/EEC as amended by Directive 2007/47/EC, a manufacturer from a third country, who does not have a registered place of business in EU seeking a CE Certification should designate a single authorized representative in the EU.

Barriers

There are no real barriers for entry in the Greek market. However, the situation with public sector hospital payment arrears has been an issue, particularly amidst the Greek economic

crisis. Many companies have witnessed long delays in the payment of accumulated debts by the Greek public sector. However, the DIRECTIVE 2011/7/EU of the European Parliament and of the Council of 16 February 2011 on combating late payment in commercial transactions has placed some increased pressure on the Greek government in proceeding with the normalization of payments in the future. Despite this directive and given the financial crisis, there continues to be public sector debt.

Trade Events

The 7th Conference + Expo—Pharmacy & Medical Management Communication + Scientific Conference on Pharmaceutical Care

February 2016 • Athens, Greece • pharmamanage.gr/en/7th_conference_expo.asp

Available Market Research

- Euromonitor International
- Business Monitor International
- Hellenic Republic Ministry of Health
- Morgan Stanley Risk Analysis
- latrikesexelixeis.gr
- European Commission

Guatemala

Summary

The United States and Guatemala enjoy a strong and growing trade relationship, especially under the U.S.-Central America-Dominican Republic Free Trade Agreement (CAFTA-DR). The United States is Guatemala's largest trading partner accounting for nearly 40 percent of Guatemala's trade.

Guatemala is a country of over 15 million inhabitants with high levels of poverty that require assistance by the public sector for its health care needs and also a large number of inhabitants that do not use public services because they can afford a private hospital or clinic. The market of medical services is divided in two segment, the private and public sectors.

- The private sector as a common rule purchases only well-known brands of medical equipment. Because of their appreciation of high quality products and a total customer support from the distributor in any emergency. Investments in new medical equipment within the private health care sector are expected to continue as new clinics and current hospitals buy periodically their equipment needs and continue to invest strongly in new technology diagnostic and treatment equipment.
- The government, in contrast, is price-driven and will purchase the lowest bidder via public tenders. All medical services in public hospitals and clinics are free of charge to any patient. This means major hospitals are replacing older equipment and buying new equipment that can meet the demand of free medical services for all the population. The public sector consists of hospitals and clinics operated by the ministry of health through the social security institute and the armed forces.



Statistics

Capital: Guatemala City
Population: 15.5 million (est.)
GDP (USD): 58.7 billion
Currency: Quetzal (GTQ)
Language: Spanish

Contact

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Market Entry

The most important decision a U.S. company has to make is to choose a local representative. The best strategy is to screen potential importer-distributors, and select the most qualified.

The chosen importer should be a company that is registered to sell to the government and can participate in official tenders and bids. Also this company needs to know the private market and have constant communication with the purchase manager of Hospitals, clinics and medical doctors with practices that use machinery.

Once the exclusive representation is given to a Guatemalan importer it is difficult to take it back because of the representation law in Guatemala, so it is necessary to have a good relationship and choose the correct representative. The legal system can be slow and the law, under certain conditions, offers local agents a great deal of protection.

Formal agency or distribution agreements should be reviewed by a Guatemalan attorney hired by the U.S. exporter (independent of the Guatemalan party with which the agreement is being established).

Current Market Trends

Consumer Preference

Hospital and clinic medical equipment is based mostly on:

- Brand name
- After sales and training of the end user
- Specifications of the equipment
- Latest technology or world trend

Differentiated Market

The final consumers or end users of the medical equipment are all the private and public hospitals and clinics in Guatemala. The difference between both markets is that private customers buy immediately and often look for the best brand of equipment meanwhile public purchases are made by bids all year long and are informed by the government via their procurement website, guatecompras.gt.

Main Competitors

Many countries compete in Guatemala; competitors vary depending on the specifications and purpose of equipment, but in general the U.S. is the most important exporter of medical equipment to Guatemala. Germany is the second major exporter to Guatemala, but is showing a decrease in almost all the categories of HS code due to the high prices of the German brands and because they export their medical equipment directly from USA because it is more convenient for delivery time. Japan and China are in third place depending on the HS code and each one with different features of price and quality in their products.

Current Demand

The total of hospitals in Guatemala is approximately 195 and the total of clinics 2,502 there is no exact number for the private sector because there is no record of it, the ministry of health only keeps record of the public sector.

All of the hospitals will need to purchase equipment in the future it is a constant procedure in the medical field so medical equipment like radiology, mammography, IMR, scanners, patient monitoring systems, digital image processing clinical laboratory equipment and dialysis equipment are going to be purchased periodically by all the hospitals and clinics in Guatemala depending on each necessity.

Medical equipment is constantly evolving and utilizing sophisticated products and most end users are looking for new technologies as well as to prefer user-friendly features in the medical machines. Also recently end users have requested companies to provide with manuals, buttons in the machines and instructions in Spanish of their equipment.

Registration Process

The Division of Registration and Control of Medicines and Foods of the Ministry of Health issues import permits for medical devices, pharmaceutical products and cosmetics.

Some products require an inscription (registration) at the registration office of the Ministry of Health. The approximate amount of time for the registration of a medical device is between 2–3 weeks and for pharmaceuticals and cosmetics is 4–6 months. These inscriptions need to be renewed every five years.

Surgical devices that require an inscription are those defined as cutting the skin or a membrane or which touch blood, such as syringes or finger pricks. Devices such as anesthetics and asthmatic inhalers, high pressure measuring apparatus, laser-guided apparatus and others do not require an inscription. These would be classified under medical equipment and supplies and undergo normal customs clearance procedures.

The Central American Technical Regulations, CATR (RTCA in Spanish) have been recently issued and published for processed food products, pharmaceuticals and cosmetics, among others. The CATR established unified standards and requirements for commercializing agricultural products, pharmaceuticals, cosmetics, healthcare products and others within the Central America and Panama region. Compliance with these technical regulations may assure that products may be imported without major complications.

For more information on these regulations, please visit bit.ly/1MszGaC or bit.ly/1U2BB7Z.

Trade Events

No local medical trade fairs, but most Guatemalan importers attend Miami's FIME International Medical Exposition (fimeshow.com).

Hong Kong Special Administrative Region

Summary

Hong Kong relies heavily on imports to satisfy its medical equipment needs. Total medical equipment imports in 2014 amounted to USD 1.68 billion. The United States was the market leader in the high-end market segment, capturing about 19 percent of the total import market in 2014.

Hong Kong is also a sourcing point for medical products for mainland China. In 2014, transshipment of medical equipment to China through Hong Kong amounted to USD 734 million; accounting for approximately 43 percent of Hong Kong's medical equipment re-exports to all destinations.

Market Entry

One of the best ways to sell healthcare devices, equipment and products in the Hong Kong market is through the use of agents or distributors. It is also an excellent way of minimizing the initial investment in the market. Working with agents and distributors in Hong Kong is very much like working with an agent in the United States. Hong Kong has no special legislation regarding agents and distributors. Virtually anything that both sides can agree to and put into a written contract is acceptable and enforceable, including restrictions on territory and a grace period for termination of the agreement.

Current Market Trends

The top deadly diseases in Hong Kong are cancer, pneumonia, heart and cerebrovascular diseases, which together accounted for about 67.5 percent of all registered deaths in 2014. Elderly people are the major victims of these chronic non-communicable diseases. As Hong Kong's aging population grows, opportunities exist for technologies that prevent and treat these diseases or reduce disability caused by them.

Statistics

Population: 7.26 million
GDP (USD): 288 billion
Currency: Hong Kong dollar (HKD)
Language: Cantonese, English,
Mandarin Chinese

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Main Competitors

U.S. healthcare technology is widely recognized as some of the most advanced available in the market today. The United States was the market leader in the high-end market segment. European, especially German, and Japanese companies are strong competitors for U.S. medical equipment and products. European medical equipment has a long record of product reliability and Japanese suppliers attend to the needs of their customers, as reflected in their product designs. Also, the recent depreciation of the Japanese yen makes Japanese products more price-competitive.

Current Demand

Hong Kong's population aged 65 or above is expected to surge from the current 1.1 million to 2.6 million by 2041. The rapidly aging population will need elder care facilities, such as nursing homes and rehabilitation centers, as well as products for the elderly.

The people of Hong Kong are becoming more health conscious and focused on preventive care, which increasingly includes routine vaccinations, screening for various cancer, high cholesterol, high blood pressure and diabetes, prenatal care and regular wellness visits.

Owing to various government campaigns, the Hong Kong public is becoming more aware of oral health. Cosmetic dentistry has also become very popular in the last several years.

Registration Process

Medical Devices

Currently, there is no specific legislative control over the importation and sale of medical devices in Hong Kong. A framework for regulating the supply of medical devices was proposed in July 2003. It is largely in line with that recommended by the International Medical Device Regulators Forum. Until the enactment of such legislation, the Medical Device Administrative Control System will continue to take effect. The Medical Device Administrative Control System features:

- A listing system for medical devices, under which manufacturers and importers of medical devices could voluntarily list their medical devices with the Department of Health.
- An adverse incident reporting system, through which the manufacturers, importers, users, and the general public could report adverse incidents to the Department of Health.

Pharmaceutical Products

Medicines to be applied on human or animal bodies for diagnosis, treatment, relief or prevention of diseases must be registered with the Hong Kong Pharmacy and Poisons Board (PBB) prior to their sale in the Hong Kong market. Pharmaceutical products are required to

conform to the standards on safety, efficacy and quality before they can obtain registration. Detailed information on the registration process is available at bit.ly/1bIVrlu.

Barriers

Hong Kong is a duty free port. There are no barriers or limitations to the import of U.S. medical equipment, devices, and products.

Trade Events

Hong Kong International Medical Devices and Supplies Fair

May 3–5, 2016 • Hong Kong • bit.ly/1bIVvl0

Showcases a wide variety of medical devices, supplies, and concepts. Organized by the Hong Kong Trade Development Council. Co-organized by the Hong Kong Medical and Healthcare Device Industries Association (HKMHDIA).

Resources

- Healthcare Procurement, bit.ly/1TUK3Gk and bit.ly/1MnWs3m
- Government Health Plans, www.vhis.gov.hk/en

Hungary

Summary

The Hungarian healthcare providers sector generated total revenues of USD 9.9 billion in 2014, and represented an annual growth rate of 0.8 percent between 2010 and 2014. The medical instruments segment has been the most lucrative over the past three years, with total revenues of USD 3.3 billion, equivalent to 32.7 percent of the sector's overall value. The outpatient care segment contributed revenues of USD 2.8 billion in 2014. The annual growth rate of the sector in the period 2012–17 is predicted to be 3.1 percent.

Hungary's health care system is mostly state-funded and its long-term policy focuses on maintaining public health care service by offering optional services through privately-operated healthcare clinics and centers. The public sector accounts for about 75 percent of the total health expenditure. The country's healthcare spending per capita almost reached USD 1024 last year, however, total health expenditure (USD 10.17 billion, 8.1 percent of GDP) is still lower than it was prior to the economic crisis, when it peaked at USD 11.4 billion. Furthermore, health spending of 2014 was 2.85 percent lower compared to 2013. 63.3 percent of total health expenditure was accounted for by the government in 2014, which was lower than previous years' ratio. As opposed to public expenditure, private healthcare spending grew faster and still continues to do so. BMI Research expects healthcare expenditure to grow at an annual growth rate of 2.5 percent between 2014 and 2019, and the Hungarian healthcare market to grow up to a value of USD 9.13 billion.

Last year the government spent USD 6.44 billion on healthcare (3.23 percent less compared to 2013), and while public healthcare expenditure was USD 3.73 billion (2.20 percent less).

Public healthcare spending accounts for 63 percent of total healthcare spending with most of it coming from a compulsory insurance scheme covering all citizens, the National Health Insurance Fund. OEP contributions are collected by the

Statistics

Capital: Budapest
Population: 9.8 million
GDP (USD): 137.1 million (2014)
Currency: Hungarian Forint (HUF)
Language: Hungarian

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national tax office, and cover most treatment and pharmaceutical costs. Restructuring of the healthcare systems started in 2011 when the government of Hungary came up with reform plans for renationalizing Hungarian hospitals that were maintained by the local government. The restructuring process was completed in 2013.

Market Entry

Medical Devices

Medical devices represent the largest segment of the healthcare sector in Hungary, accounting for 32.7 percent of the sector's total value in 2013. The outpatient care segment accounted for a further 27.7 percent of the sector. Hungary is part of the EU External Tariff System. According to Hungarian tax regulations, all products, regardless of origin are subject to an extremely high (27 percent) value added tax which is borne by the final customer (by the hospital or by the patients). The EU directives on Medical products have been integrated into Hungarian legislation. Generally, there must be one Authorized Representative in one of the EU countries, who is responsible for the EU-wide CE mark. Prior to entering the Hungarian market, medical products must have the CE mark. If a medical product has the CE mark issued by an eligible notified body, no further testing is required by any Hungarian authority. If the product has no CE mark, a Hungarian notified body can issue it. According to Hungarian regulations, foreign suppliers are required to have a Resident Representative in the country responsible for the foreign product. The Hungarian partner is required to register the product with the Authority for Medical Devices (c/o Ministry of National Resources) and provide the necessary information including directions for use and labeling in Hungarian. The resident representative keeps the technical files and is the point of contact for market surveillance. The Hungarian market is receptive to high quality, innovative U.S. medical devices and diagnostic instruments.

As Hungarian health care system is widely felt to be under-financed, foreign companies have a competitive edge if they offer financing. The number of clinical trials in Hungary has been on the rise over the recent years. Medical products are marketed in Hungary through authorized and exclusive distributors. Major foreign companies either have their own subsidiaries or operate through local distributors. Most distributors handle several brands of similar equipment or several lines. Pricing is a key factor in selling medical products in Hungary, as the market is very price sensitive. When purchasing medical equipment, end-users also look for established companies with reliable and efficient after-sales service and customer support.

Drugs

Registration of all medicines intended for human use including homeopathic preparations, preparations marked with isotopes and immune-biological preparations, vaccines and blood products is carried out by the National Institute for Quality and Organizational Development in Healthcare and Medicines (GYEMSZI, gyemszi.hu).

Current Market Trends

Imports dominate the very competitive Hungarian market for medical supplies and equipment, and the value of imported medicines has also increased over the past 20 years. Over 80 percent of an estimated USD 801 million (2013) is spent on foreign products. According to industry estimates of the Association of Medical Technology in Hungary, roughly and only 23 percent is spent on high-value devices, another 29 percent for rehabilitation products and the rest for medical equipment and hospital supplies. Hungarian companies supply local products for about 15–18 percent of the medical equipment and supply market. There are about 150–160 small and medium-sized medical companies in Hungary, most of them specialized in high-tech products for export markets and in Research and development activities with a staff of less than 20 people. Electro-medical devices, blood sugar meters, urine analyzers, neonate therapeutic devices are the largest products by export value. U.S. products account for approximately 15–17 percent of total medical technologies imports. In addition to the official statistics, a number of European subsidiaries of U.S. companies are shipping products to Hungary registered as goods from Germany, England, the Netherlands, and the Scandinavian countries. A few U.S. companies have their own representative, sales offices or even manufacturing and Research and development centers in Hungary like GE Healthcare, Varian or Fluke, while most distribute their products through local companies. Medical products imported from the U.S. in significant amounts include electro-medical instruments; disposables like catheters; ultrasound machines; diagnostic equipment and instruments; orthopedic appliances and implants, hearing aids and pacemakers.

As mentioned before, pharmaceutical imports have also been significant in the last 20 years, it shows steadily decreasing trend. As cost containment and economic austerity became more and more important, the pharmaceutical sector had to endure several significant cuts in expenditure, alongside with pricing pressure on its manufacturers. The demand for imports declined in the last two two years, and imports only showed slight increase of 1 percent in 2014.

BMI Research voices concerns regarding export outlook, as the growth expectations worsen in Central and Eastern Europe. Russia and Ukraine have been growth drivers for CEE exporters, including Egis and Richter Gedeon, the crisis between the two countries will also impact their import demand.

Main Competitors

The import of medical products is fully liberalized. U.S. companies face stiff competition from West European and Japanese companies in Hungary. German, Austrian, Italian and British companies have been present for many years in the market. Germany has been the sales leader for decades with over 20 percent market share in the overall medical market. The proximity of the European companies to the Hungarian market allows them frequent visits to meet end users, to participate in exhibitions and scientific meetings, and to provide prompt after-sales

services to buyers. Some of them have established manufacturing units in Hungary for serving their Central-Eastern European markets.

Current Demand

Medical Devices

Funding from EU structural fund has been used for priority healthcare development projects, including development of outpatient clinics (funds for 19 regional outpatient clinics has been approved), development of one-day surgery, development of high-priority hospitals for the regions, and upgrade of emergency care. Opportunities for U.S. medical equipment suppliers include ultrasound equipment, digital X-ray, monitoring equipment, MR, CT, nuclear imaging (PET, Gamma camera), laboratory diagnostics, and clinical chemistry.

Dental Equipment and Supplies

With close to 5,800 practicing dentists (out of 6,000 registered) in 2014, Hungary is a market leader in providing dental services for dental tourists. It has a market share of 42 percent, closely followed by Poland (31 percent), Turkey (15 percent), Spain and Bulgaria with 7 percent. The size of the Hungarian dental equipment and supply market reached about USD 34 million. It has grown significantly and the dental tourism is 15 years ahead in Hungary compared to other countries in Europe. Hungary is the third country in the world in the dental tourism after Mexico and India preceding Poland, Thailand and Turkey. Most dental tourists come from Germany, Great Britain, the Scandinavian countries, Italy and France. In terms of imports the market is dominated by Austrian, German, British, Scandinavian, Italian, French and Japanese suppliers however it provides market potential for U.S. suppliers of teeth whitening systems, lasers, optical instruments, implant instruments, root canal treatment, computer-controlled injection devices for anesthetization, and orthodontics devices. The dental tourism has been contributing to the Hungarian economy growth and resulted in HUF 90 billion revenue in 2013, Hungary attracts the third biggest number of dental tourists in the world, mainly from neighboring countries and Great Britain.

E-Health

In the framework of the National Development Plan, European Funds are allocated to various healthcare expenditures including specific IT related projects. Best prospects include the E-Health Card, E-Patient Registration system project that will require the supply of about 40,000 card readers, a card management system, card application and authentication solutions and the Electronic authentication database and healthcare portal project requiring security and authentication solutions.

Drugs and Pharmaceuticals

Hungary's domestic pharmaceutical sector is prosperous, both in term of domestic sales and trade—pharmaceuticals is the fourth largest field concerning export. Highly educated workforce with relatively cheap wages and government support attracting investors are just

some examples of the numerous advantages of this key industry in Hungary. On the other hand, a series of policy changes bringing pricing pressures and higher taxes has damaged innovative and generic drug producers alike in recent years. Furthermore, the government own a significant part of drug producer Richter Gedeon, which causes concerns regarding preferential treatment.

Drug sales amounted to USD 2.4 billion in 2013. Imported medicines accounted for 64 percent of sales, worth USD 1.7 billion. As of December 2013, there were 5,118 registered drugs on the Hungarian market, out of which 3,380 were prescription medications. In 2013, the number of subsidized drugs reached 4,800. The number of over-the-counter (OTC) medications rose to 1,870 in 2012. In terms of total sales, prescription drugs dominate the market with approximately 72 percent of the market share. Roughly four-hundred OTC products can be sold outside pharmacies in drug stores and large hypermarkets as well. There is no import duty levied on pharmaceutical products, and a 5 percent VAT must be paid by consumers.

BMI Research states that the Hungarian pharmaceutical market to grew by 2.2 percent in 2014 to USD 2.66 billion, which includes over-the-counter drugs and reimbursed, non-reimbursed and hospital medicine sales. Pharmaceutical expenditure fell by 0.03 percent, and the government still aims to reduce the health spending going on pharmaceuticals in order to minimize rising imports, consumption volumes and prices.

Barriers

Companies exporting medical devices to Hungary will not encounter any direct trade barriers or quotas. Non-tariff, indirect trade barriers, however, affect the pharmaceutical manufacturers including a 20 percent tax on reimbursed sales of pharmaceutical products, a non-proportional annual fee of HUF 10 million (about USD 54,000) for every pharmaceutical sales representative, and a claw-back, mandating that pharmaceutical manufacturers repay the government for up to 100 percent of pharmaceutical over-expenditures by the National Health Insurance Fund (NHIF). In order to meet the requirement of the convergence plan and keep the budget deficit under 3 percent, the government plans a HUF 150 billion (USD 750 million) cut in the Pharmaceutical Fund over the past four years that seriously affects innovative pharmaceutical manufacturers in the market. If there is an overspending in the pharmaceutical budget, the NHIF determines which pharmaceutical manufacturer's market share has increased compared to the base year. Any company whose turnover has exceeded the market share of the baseline year has to pay this claw-back on the basis of a complicated formula.

Trade Events

Dental World 2015 Budapest

October 1–3, 2015 • Budapest, Hungary • dentalworld.hu

India

Summary

Indian Medical Devices and Equipment Market, 2012–15				
(USD Millions)	2012	2013	2014	2015 (proj.)
Total Market Size	5189	5812	6509	6942
Total Local Production	2670	2767	2800	3619
Total Exports	75	91	151	148
Total Imports	2594	3136	3860	3471
Imports from the U.S.	496	509	522	509

Source: Unofficial estimates from trade sources and industry; as this industry has not been well documented, estimates vary significantly across different sources. Additional information from the U.S. Census Bureau

The Indian healthcare sector is experiencing a rapid change. Though this change has been under way for many years it has become significantly visible in the last decade, with a renewed thrust from both the government and a growing market for healthcare services and products. Rapid economic growth, rising middle class incomes and a surge in lifestyle diseases have created a booming life science market. According to the World Health Organization (WHO), Indian per capita health spending stands at just USD 132 (on a PPP-adjusted basis), ranking 145th amongst WHO nations and less than 2 percent of the USD 8,632 spent in the United States. India's annual healthcare expenditure stands at just USD 77 billion, against USD 300 billion in China, despite the fact that India is expected to surpass China as the most populous nation in the next 20 years.

The Indian Healthcare industry which comprises hospitals, medical infrastructure, medical devices, clinical trials, outsourcing, telemedicine, health insurance and medical equipment is amounted to USD 96 billion in 2013 and expected to reach USD 280 billion by 2020, due to increase demand for specialized and quality

Statistics

Capital: New Delhi
Population: 1.22 billion
GDP (USD): 5.07 trillion
Currency: Indian rupee (INR)
Language: Hindi, English

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healthcare facilities. The market is dominated by private players. The industry is rapidly developing and is being fueled by large investments from existing corporate hospital chains and new entrants backed by private equity investors. This growth will be driven by healthcare facilities, private-public projects, medical diagnostic and pathological laboratories, and the health insurance sector. In addition, changing demographics, disease profiles and the shift from chronic to lifestyle diseases in the country has led to increased spending on healthcare delivery.

Market Entry

In India, healthcare is delivered through both the public sector and private sector. The private sector's contribution to healthcare has been growing at a faster pace than government. There are no restrictions on foreign direct investment in healthcare services. Import of medical equipment is allowed under the "Open General" category of the Import regulations, except for nuclear medicine. Customs duty levied on imported products depends on the product classification, for some devices the duty has been brought down from 25 to 5 percent. Products classified as "life saving equipment" have reduced duty applicable on them to encourage hospitals to import latest equipment.

Price, quality and after-sales service support are major factors in medical equipment purchase decisions. Letter of credit is usual the mode of payment for imports. Purchase decision in government follow a tendering process and is time consuming, while it is faster in the private hospitals.

Current Market Trends

India's population of over one billion people is growing at a rate of 1.6 percent per year. An ageing population of over 100 million, with rising incidence of lifestyle diseases, which combined with rising incomes and increased penetration of health insurance are fuelling growth of the industry. Considerable challenges exist in terms of service accessibility and patient care quality. As such government support would inherently play a significant role in the overall development and growth of the sector.

High upfront investments, long gestation periods, and rising real estate costs are compelling private players to innovate with business models and expand into under penetrated tier II and III cities. As a result, these private players can capitalize on the opportunity to expand. The private sector is likely to contribute 80–85 percent of the USD 86 billion healthcare investment required till 2025.

The Indian medical device market is worth an estimated USD 3.2 billion (without the inclusion of the rural market potential) and expected to reach USD 5 billion by 2016. The medical device industry is a very attractive export sector for U.S. companies, which account for one quarter of exports to India. India imports nearly 80 percent of its medical devices and barriers to

entry are low compared to other industries, despite a 4 percent additive import tax placed on most categories of devices in 2007. India remains highly dependent on imports for many types of medical devices, particularly higher end products that include cancer diagnostics, medical imaging, ultrasonic scans, PCR technologies. Imports are growing rapidly as world-class hospital groups such as Fortis and Apollo build high-end infrastructure and open India to medical tourism, which now adds USD 2 billion to the Indian healthcare market.

Health insurance is gaining high momentum in India. Currently 15 percent of the population is covered by government health insurance companies and 2 percent by private health insurance. For the purpose of regulation, health insurance companies are classified as non-life companies. General Insurance companies are called as Non-Life companies in India. This penetration of health insurance will significantly increase the affordability of healthcare services for the population. Several private insurance companies have entered the market and have empanelled hospitals to provide cashless treatment to subscribers of insurance companies.

In India, healthcare is provided through primary, secondary and tertiary care hospitals. The first two categories are fully managed by the government. While the tertiary care hospitals are owned and managed by either government or private sector, the private sector's contribution to healthcare has been growing at a faster pace than government. The medical infrastructure market is estimated to have a growth rate of 15 percent. Both the government and private sector are planning several new specialty and super-specialty hospital facilities, modernization of existing hospitals. India currently faces a chronic shortage of healthcare infrastructure, especially in rural areas and Tier II and Tier III cities, and it is expected that India will have potential requirement of 1.75 million new beds by the end of 2025. The opportunity also exists for overseas organizations to set up hospitals in India through the Foreign Direct Investments. The hospital services market, which represents one of the most important segments of the Indian healthcare industry, is expected to be worth USD 80 billion by 2015.

The new specialty and super-specialty hospital facilities depend on the import of high-end medical equipment, accounting for over 65 percent of the entire market. There is a need for sophisticated hospital equipment, especially operation theatre products and training through simulation labs. In view of the relatively low customs duty rates (9.2–15 percent) combined with an increasing number of healthcare centers specializing in advance surgery, India offers opportunities for the direct supply of high-technology, specialized medical equipment, products and systems.

Biotech is one of the fastest growing segments of the life sciences sector. The market currently stands at USD 3.2 billion and is growing over 20 percent per year. If the current trends continue, the biotech market could reach USD 8 billion by 2015. The biotech sector represents a diverse opportunity for international companies.

The boom in medical tourism in the Indian healthcare sector is encouraging hospitals and hoteliers to strike alliances with each other. Presence of world-class hospitals and skilled medical professionals has strengthened India's position as a preferred destination for medical tourism. According to the industry estimates, Medical tourism market is expected to expand at a CAGR of 27 percent to reach USD 3.9 billion in 2014 from USD 1.9 billion in 2011.

E-healthcare/Telemedicine, though in its infancy in India, is beginning to take root. Most public hospitals (funded by State governments) and private single and multi-super specialty hospitals have gone in for customized Hospital Management Systems and other medical based IT products. Given the poor availability of quality healthcare facilities outside the large and second tier cities, telemedicine is expected to become a viable business proposition. Several major private players like Apollo, AIIMS, and Narayan Hrudalaya have adopted telemedicine services. With increased private participation, the healthcare sector has also witnessed rise in FDI inflows. The government of India has permitted 100 percent FDI for all health-related services under automatic route.

Main Competitors

The large private healthcare services providers are actively seeking growth by enhancing their reach across the country through the building new hospitals and acquiring and upgrading existing hospitals. There are several groups operating hospital chains including Apollo Group, Fortis Healthcare, Manipal Group, Max Healthcare, Medanta-Medicity, and Wockhardt Hospitals. In the medical equipment segment competition is from the imports from European companies and Japan. India being a price sensitive market there is competition from low priced Chinese products.

Current Demand

The growing demand for quality healthcare and the absence of matching delivery mechanisms pose a challenge and certainly a great opportunity. In Infrastructure—building, equipping, managing and financing the super specialty hospitals in India through the FDI route is another area for future growth. Some best sales prospects in the medical equipment market include medical and surgical instruments, medical imaging, electro medical equipment, orthopedic and prosthetic appliances, cancer diagnostic, orthodontic and dental implants equipment, ophthalmic instruments and appliances, Point of Care Testing (POCT) diagnostic devices.

A proper supply of equipment and medical consumables will also be an area with significant for U.S. companies. Several leading U.S. purveyors of hospital equipment and supplies have opened Indian operations to cater to this growing market.

Health insurance and hospital administration is another area in which U.S. companies can make a difference. This opportunity includes introducing and maintaining industry standards, and also classifying and certifying healthcare centers.

Other growth areas include diagnostic kits, reagents, hand-held equipment and stimulation for operation rooms. Imports constitute 50 percent of this market. Hand-held/portable diagnostic equipment (e.g. for blood sugar or blood pressure testing) is also a fast-growing segment since India has around 46 million diabetics, which is expected to swell to 70 million by 2025.

Registration Process

The Central Drugs Standard Control Organization (CDSCO) is the key regulatory organization in India. Import of medical devices into India still remains largely unregulated, though the Indian government has adopted some measures in recent years to change that. With the final procedures and guidelines not being laid down as yet, things are actually pretty confusing at this stage. Currently, the Ministry of Health and Family Welfare has notified only 14 devices that are regulated: bit.ly/1b88V6e.

Visit bit.ly/18DIOGI for more information on import regulations and the registration process.

The CDSCO drug controller provides detailed information on medical device import regulations and registration requirements. Please visit cdsco.nic.in for more information.

Barriers

To ensure quality healthcare, in October 2005 the government of India increased a list of medical devices covered under the Drugs and Cosmetics Act of 1940, bringing fourteen categories of implantable devices under regulatory control. These include:

- Cardiac stents
- Catheters
- Intravenous cannulae
- Drug eluting stents
- Intra-ocular lenses
- Scalp vein set
- Heart valves
- Hip and knee implants and bone cements
- In-vitro diagnostic devices

An improved central licensing authority must license these devices for manufacture, sale, or distribution.

Hospitals are also seeking quality accreditations such as JCI, NABH and ISO.

Trade Events

Medical Fair India

March 11–13, 2016 • Mumbai, India • medicalfair-india.com

Medicall

2016 • Chennai, India • medicall.in

Resources

- Ministry of Health and Family Welfare (MOHFW), mohfw.nic.in
- Indian Medical Association, ima-india.org
- The Medical Council of India (MCI), mciindia.org
- Medical Pharma Healthcare Tenders in India, medicaltenders.com/medical_tenders_india.htm
- Health IT in India, bit.ly/1llaQrn
- U.S. Healthcare Export Growth to India, onforb.es/1MqDbil

Indonesia

Summary

As the fourth most populous country in the world, Indonesia offers great potential in the medical equipment and supplies market. In 2014, the market is estimated at USD 793 million. The market shows consistent growth and is expected to reach over USD 870 million in 2015. About 97 percent of the Indonesian medical device market is made up of imports. Healthcare is a top priority in Indonesian's national development agenda. The central and regional governments continue to build and upgrade healthcare facilities and improve their quality of service in the 33 provinces. In April 2015, 15 community health centers (Puskesmas) were upgraded to type "D" hospitals in Jakarta. Twenty nine more such facilities are expected to be upgraded in the future. The government continues to encourage private sector involvement in developing hospitals. In the next five years, the private sector plans to develop over 30 hospitals. Indonesia began implementing its National Health Insurance Plan in 2014 year with the goal of universal coverage of the country's population of 254 million people by 2019. Given the large population and the implementation of the universal social health insurance coverage, Indonesia should remain a good market for healthcare products.

General economic challenges should be noted. The Indonesian economy continues to stagnate on reduced domestic demand and moderate increases in inflation. Government spending has failed to keep up with expectations and has negatively impacted both the stock market and GDP calculations. The decline in the Rupiah against the Dollar seems to have stabilized at this point but the positive balance of significantly reduced trade highlights serious hurdles for the revival of the Indonesian economy in this post-commodity boom era.

Market Entry

Local agents/distributors handle registration for the products and play an important role in developing the market and providing after-sales services. U.S.

Statistics

Capital: Jakarta
Population: 254 million (est. 2014)
GDP (USD): 868 billion (est. 2014)
Currency: Indonesian Rupiah (IDR)
Language: Indonesian

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companies must either establish a foreign investment company in the form of a PT (limited liability company) or appoint one or more Indonesian agents/distributors to market and sell their medical equipment and supplies in Indonesia.

Current Market Trends

Healthcare providers show a growing interest in high technology equipment to improve the delivery and quality of their services. The government is encouraging more private sector involvement. Major property developer Ciputra Group plans to build up to 10 hospitals within the next five years with an estimated investment of USD 130 million. In September 2013, the Siloam Hospital Group announced that they plan to spend USD 400 million through 2017 to develop new hospitals including purchases of medical equipment. The group will open three new hospitals by the end of 2016. In January 2015, the Jakarta Health Agency announced plans to build a cancer treatment hospital in Jakarta, which is expected to become operational in 2017.

Main Competitors

The market for medical equipment and supplies is highly competitive. U.S. exports account for 10 percent of this market. Other countries vying for market share of medical equipment and supplies in Indonesia include Singapore, Japan, Germany, China, and Korea. Companies from China and Korea provide the greatest challenge to U.S. companies as they offer low-priced equipment. Therefore, while quality and after-sales service are essential elements, it is also important to price products competitively.

Current Demand

Best prospects include:

- Diagnostics and laboratory reagents
- Compact/modular laboratory automation for clinical chemistry
- Electro-diagnostic equipment, ultrasonic scanning machines, and x-ray units
- Rapid tests for HIV, TB, and other infectious diseases
- ICU, ICCU, and life support equipment such as ventilators, anesthesia and patient monitoring equipment

Registration Process

Foreign companies must be prepared to operate in an often uncertain regulatory environment. Product registration can be lengthy, and new and changing requirements can hamper market entry, such as labeling and local content requirements. A strong local distributor or partner is critical to help navigate the product registration process and stay abreast of changing regulations.

The Indonesian Ministry of Health (MOH) controls the registration of medical devices and household health supplies in Indonesia. In general, products that are FDA-approved and sold in the U.S. will be approved to enter the market in Indonesia. The process to obtain the license may take over six months. Imported medical devices and supplies must be registered with the MOH before clearance through Customs.

Medical equipment importers must submit a registration application to the Ministry of Health which includes all of the following documents that the U.S. company should supply:

- Letter of Authorization issued by the manufacturer, legalized by the Indonesian Embassy and a notary public in the U.S.
- Certificate of Free Sales from the authorized institution.
- Certificate of CE for CE mark products or Certificate of ISO for ISO mark products, if any
- Product Information—formula/ component/raw materials and brief manufacturing process flow chart
- Finished product specifications
- Safety and Efficacy Data
- Instructions for use, which will be translated into the Indonesian language

Barriers

There are no restrictions on imports of medical equipment; however, imports of used equipment are prohibited. Medical equipment is subject to a 0–5 percent import tax and a value-added tax of 10 percent. The Ministry of Health controls the registration of medical equipment in Indonesia. In general, products that are FDA-approved and sold in the U.S. will be approved to enter the market in Indonesia.

Trade Events

Hospital Expo 2015 Jakarta

October 21–24, 2015 • Jakarta, Indonesia • hospital-expo.com

Ireland

Summary

Ireland has a dual healthcare system, consisting of both private and public healthcare options. The public healthcare system is regulated by the Irish government's Health Service Executive. In 2015, the budget for the Irish health service was EUR 13.409 billion plus a capital budget of EUR 382 million. The Irish healthcare market maintains a strong affinity with the U.S. as many of its doctors and consultant specialists are trained at leading U.S. healthcare facilities. Strong relationships also exist between U.S. and Irish universities and hospitals.

Just over two million people have private health cover in Ireland, down from almost 2.3 million in 2008. A total of 1.36 million people with low incomes and those over the age of 70 with modest incomes are entitled to avail of a free medical card scheme. Charges apply for visits to a local doctor except for approved medical card holders. With a move towards a Universal Health Insurance model, free medical doctor care is now also available for under sixes and over 70's.

Market Entry

Ireland, as the only English-speaking member of the Euro-zone, serves as a natural test market and location from which to begin distribution throughout Europe. U.S. medical device products are well regarded in Ireland, with the market being highly receptive to U.S. medical equipment/technologies.

U.S. companies exporting to Ireland should obtain local representation through an agent or distributor, of which there are 100 plus qualified companies in Ireland. CE marking is a legal requirement in Ireland. Irish labeling requirements are similar to those used elsewhere in the EU, except Irish authorities require the name and the EU address of the manufacturer, distributor or packer to also appear on the label. Ireland applies EU tariffs (customs duties) which are based on the international Harmonized System (HS) of product classification. Duty rates on manufactured

Statistics

Capital: Dublin
Population: 4.6 million
GDP (USD): 241 billion
Currency: Euro (EUR/€)
Language: English

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goods from the U.S. generally range from 5–8 percent and are usually based on the c.i.f. value of the goods at the port of entry.

The standard electricity voltage in the Republic of Ireland is 230V a.c., nominal, at 50Hz, with plugs being of the 3-pin IS411 (BS 1363) type. Any electrical item sold on the Irish market should include a 3-pin plug attached (molded) to the power cord. Exporters selling electrical products in the EU must conform to the WEEE and RoHS directives.

Current Market Trends

The Irish government is an advocate of preventative medicine focusing on breast, cervical and colon cancer screening. A National Diabetes Retinopathy Screening is available for those with diabetes aged over 12 years. The aging population will generate opportunities in living aids and assistive technology. Significant hospital budget over-runs means that the introduction of innovative products and technologies need to prove substantial cost efficacy and efficiency in competition with the equipment replacement market. Opportunities exist for equipment that saves time, resources, and produces cost savings in a price sensitive market.

Main Competitors

International brands have local sales and marketing operations or utilize an extensive network of Irish distributors. Most of the leading U.S. and international medical device companies service the Irish market together with a growing group of indigenous manufacturers.

Current Demand

The establishment of hospital groups as part of the reform of the Irish acute hospital system is aimed at streamlining procurement and the provision of services. New opportunities for U.S. companies will be generated with the opening of a new 445-bed National Children's Hospital (due 2019) and a network of new primary care centers.

Registration Process

The Irish Health Products Regulatory Authority (HPRA) monitors medical devices for safety and quality concerns once placed on the market and they regulate medical device manufacturing, wholesale and distribution companies and medical device notified bodies. Most medical devices are initially assessed and approved by a separate organization called a "notified body." Medical devices that have been approved have to bear a CE mark—this indicates it meets the basic requirements for safety and effectiveness under European law.

Barriers

Companies exporting medical devices to Ireland will not encounter any direct trade barriers or quotas.

Trade Events

Med in Ireland 2015

October 29, 2015 • Dublin, Ireland • medinireland.ie

MEDTEC Ireland

October 6–7, 2015 • Galway, Ireland • medtecireland.com

Resources

- Healthcare Procurement, etenders.gov.ie
- Department of Health, health.gov.ie

Israel

Summary

Under the U.S.-Israel Free Trade Agreement (FTA), U.S. goods face no import duties upon entering Israel's market. Proper Shipping documents and a Certificate of Origin for Exporting to Israel are required in order to benefit from the FTA. Every product is still subject to 18 percent Value-Added-Tax (VAT). VAT is levied on the CIF landed cost.

Current Market Trends

Aging Population

The aging population creates multiple challenges for Israeli society. The need to cope with the steadily increasing number of elderly with dementia is one of Israel's healthcare system major challenges. The Ministry of Health developed a national strategic plan to Address Alzheimer's and other types of dementia. The recommendations offer a holistic perspective and emphasize collaboration among all relevant agencies: government ministries, the health plans and other organizations. The Strategic Plan aspires to cope with key issues that make it difficult for the current service system to provide an appropriate response to the unique needs of dementia patients.

Increasing Private Health Spending

The proportion of private financing in national health spending in Israel, on top of the health tax, continues to rise. According to the Israel Central Bureau of Statistics, the proportion of private spending is 40 percent, making it one of the highest rates in the Organization for Economic Cooperation and Development (OECD), in which the aggregate rate of private health spending is only 28 percent. The trend is clear and consistent, resulting from an erosion of the system's resources. Meanwhile, the public's spending on health insurance and private medicine in general grew.

Private spending is composed of payments for dentistry (most dentistry in Israel is not included in the state health basket), supplementary and commercial health

Statistics

Population: 8.3 million
GDP (USD): 305 billion
Currency: Shekel (ILS)
Language: Hebrew, Arabic

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insurance, private care, purchases of medications, deductible payments and purchases of medical equipment.

The rate of public spending has not changed since 1995. The government refrains from increasing the health system's financial resources, despite population growth and technological requirements. Among other things, every purchase of an MRI machine, or a machine used in cancer radiology treatments, requires a special license. The rationale for this policy on diagnostic imaging devices like an MRI may very well be understandable, since increasing the supply can increase the demand, including unnecessary diagnoses.

Main Competitors

Israel is a sophisticated and mature market. U.S. suppliers face intense competition and should therefore be ready to compete and support their local distributors through educational presentations, material and lobbying/advocacy. Major multinationals and large companies have established direct sales and marketing offices in Israel. Other exporters operate through local distributors. There are hundreds of medical distributors that are well-established throughout the country.

Current Demand

Israel has a growing elderly population and limited resources. As a result, the demand is for cost-saving products and for products that help patient monitor their health at home. Wound care, advanced diagnostics and minimal invasive procedures continue to be a high priority in the public healthcare market. In addition, a well-developed private sector health care in the areas of dental, eye laser surgery and plastic/aesthetic surgery keep up the demand for advanced medical instruments and appliances. Israel has an excellent digital health tech base and is a world leader in mobile and E health implementations. Opportunities exist however, in further advancing drug monitoring and disease surveillance. Other best sales prospects include minimally invasive surgical instruments and technologies that are integrated with imaging capabilities, cardiology equipment, equipment and supplies for plastic surgery, smart implants, dental instruments, equipment and technologies for pain management, physiotherapy, ozone and oxygen therapy, operating room equipment and cost-saving single use products, point of care diagnostic kits and wound management technologies.

Registration Process

Market access is fairly clear for U.S. FDA and CE Marked medical products. U.S. companies interested in exporting to Israel need to appoint a local distributor, agent or other legal representative to register their products with the Israel Ministry of Health. The device registration should be accompanied by a 510(k), Pre-Market Approval (PMA) or an Investigational Device Exemption (IDE). The Ministry of Health has an overarching regulatory and policy making role.

Barriers

All tariffs on trade between the U.S. and Israel have been eliminated since 1995. The Israel Ministry of Health uses the FDA's standards for the purpose of issuing licenses. Import permit procedures for U.S.-made, USFDA-approved medical equipment are fairly easily facilitated. There are many suppliers so U.S. companies should be ready to compete.

Trade Events

Life Science Industry Event (LSIE)

December 9–10, 2015 • Tel Aviv, Israel • stier-group.com/lsie/index_en.asp

Innovations in Cardiovascular Interventions (ICI) Meeting

December 13–15, 2015 • Tel Aviv, Israel • 2015.icimeeting.com

MEDinISRAEL 2016

March 2016 • Tel Aviv, Israel • medinisrael2015.com

BioMed Israel 2016

May 2016 • Tel Aviv, Israel • biomed.kenes-exhibitions.com



Italy

Summary

Italy is a mature market for medical equipment, and its high per capita income and sophisticated healthcare system translate into demand for a broad range of cutting-edge medical equipment. The Italian market for medical equipment and supplies is the fourth largest in Europe following Germany, France, and the UK, with about 3,000 companies including distributors (56 percent), producers (40 percent), and service providers (4 percent), as well as a workforce of 54,000 people. The medical device market (including dental and optical devices) was valued at approximately USD 9.2 billion in 2014, with imports accounting for USD 6.2 billion. Aside from other medical devices, consumable products represent the largest market segment (20.9 percent), followed by diagnostic imaging (15.5 percent) and patient aids (15.1 percent).

The Italian government is the primary purchaser of medical equipment. Public hospitals account for over 75 percent of medical device sales, while the remaining 25 percent of sales are made to the private sector. Despite having a considerable local manufacturing industry, the domestic market for medical equipment is highly dependent on imports. Major suppliers are the Netherlands, Germany, Belgium, France, and the United States (which had a 6.6 percent share of Italian imports, valued at USD 411,583 million in 2013). Major U.S. imports are in diagnostic imaging, dental products, and patient aids.

Market Entry

The Italian government has implemented various European Union (EU) directives related to medical devices, and U.S. companies must be prepared to comply with Italian and EU legislation.

Statistics

Capital: Rome
Population: 61.1 million
GDP (USD): 1.77 trillion
Currency: Euro (EUR/€)
Language: Italian

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U.S. companies interested in entering the Italian market should carefully select their potential distributors or agents, and should also consider cooperative arrangements or joint venture/licensing agreements with Italian partners.

Regional governments issue specific regulations governing the procurement of medical equipment. Most purchases are made by public tenders open to both domestic and foreign companies. Announcements of tenders on public procurements are monitored by the U.S. Mission to the European Union.

All medical devices marketed in the EU must bear the CE mark. Member states have appointed certification authorities ("notified bodies") to grant compliance certificates. Award criteria are typically based either on the lowest price or on the most economical quotations.

Current Market Trends

The Italian domestic medical market (including dental and optical medical devices) was estimated at approximately USD 7.1 billion in 2014. Major constraints to the sector development are the healthcare cost-containment measures together with the late payment of public hospitals counting for 70 percent of the medical devices sales. Italy imports primarily from The Netherlands (23 percent), Germany (19.2 percent), Belgium (13.9 percent) France (11.4 percent) and the United States (6.6 percent). Italy has a strong position in major subsectors including biomedical instruments and electro medical diagnostics. Regions with the highest concentration of medical devices companies are in Northern Italy.

Main Competitors

Foreign companies represent 8.2 percent of the total number of companies producing medical devices. Industry giants such Siemens, Philips, Hitachi and Toshiba are well represented in the market. A significant number of U.S. manufacturers of medical equipment are also present in the Italian healthcare market (about 60 companies with 5,700 employees and USD 2.7 billion domestic revenue). Some U.S. suppliers maintain wholly owned subsidiaries in Italy and sell equipment imported from the United States or from plants in other foreign countries, such as Johnson & Johnson, Medtronic, and GE Healthcare.

Italian companies are typically small or medium-sized, and are mainly concentrated in Lombardy, Emilia Romagna, Veneto, Lazio, Toscana and Piemonte. The sector is highly innovative; there are about 214 start-ups, and 67 percent received public financing.

Current Demand

Medical Devices

The best sales potential for U.S. manufactured medical equipment is in the following areas: home care equipment, remote monitoring equipment, high frequency medical lasers (for multiple applications), endoscopes and diagnostic imaging equipment non-invasive and

micro-surgery devices and equipment, anesthesiology equipment, EKG, stimulators and defibrillators, ophthalmic equipment, monitoring equipment, telemedicine equipment and services. The Italian market is receptive to high quality and technologically advanced diagnostics and therapeutic equipment and products.

With increasing attention to reforming and improving healthcare management, medical devices companies providing add-on services and solutions will also have opportunities in the Italian market. The services will enhance the value proposition of existing products for patients (e.g. services to identify the appropriate patients for the use of a device, training for nurses on new procedures and products, partnership with hospitals to increase efficiency).

E-Health

The European e-Health market has an estimated annual value of around USD 20 billion with an annual growth of 3 percent. Considering that the demand for healthcare products and services will rise significantly in coming years, the information technology applied to the healthcare systems is a key enabler for delivering more effective and efficient health care. In Italy, the ICT expenditures in healthcare are estimated at USD 1.8 billion corresponding to 1.3 percent of the total healthcare expenditures, which is limited compared to other countries (2.5 percent to 3 percent). However, after years where the ICT expenditures have been declining, in 2014 the ICT budget grew in all sectors: USD 1.2 billion spent by the healthcare organizations, USD 422 million spent directly by the regions, USD 88 million spent by over 47,000 general practitioners and USD 26 million by the Italian Ministry of Health.

Strategic areas which will see investments over the next 3 years include electronic health records, cloud computing, administrative management, digital management of drugs, ePrescription, mobile health, and business intelligence and clinical governance.

Registration Process

All medical products and equipment imported into Italy require a notification to the Italian Ministry of Health (MOH). The designated competent authority for medical devices is the Directorate General of Medical Devices and Pharmaceutical Services at the Ministry of Health. All new-to-market medical devices must go through an on-line device registration process with the Italian Ministry of Health to be placed in the Italian market. Information on registration procedures is available at bit.ly/1eKoBBY.

Barriers

There are no other significant trade barriers or limitations on imports of U.S. goods. Technical specifications are essentially those established by the EU, which have been incorporated into Italian law. Official technical norms are issued by UNI, the Italian Standards Institute, and electrical norms are from CEI, the Italian Electro technical Standards Institute.

Resources

- Healthcare Procurement (national), bit.ly/1OX8SR3
- Healthcare Procurement (regional), bit.ly/1JjrCbb
- Government Health Plans, bit.ly/1g9AKUO

Trade Events

Exposanità

May 18–21, 2016 • Bologna, Italy • bit.ly/1RsAcWN

Europe's second-largest medical device trade show. Approximately 29,200 visitors and 720 exhibitors.



Japan

Summary

Japan's market for medical devices and materials continues to be among the world's largest. According to the latest official figures from the Ministry of Health, Labour and Welfare (MHLW) Annual Pharmaceutical Production Statistics, the Japanese market for medical devices and materials in 2013 was approximately USD 33.6 billion (up 3.2 percent from 2012 in yen terms). Japan's total imports of U.S. medical devices were approximately USD 7.7 billion in 2013. In the near term, the market is expected to increase due to Japan's aging population and continued demands for advanced medical technologies. The market remains heavily dependent on imports, especially sophisticated medical technologies. U.S. exports to Japan have a 23 percent total market share according to the official figures. However for advanced devices and diagnostics, the total market share of U.S.-origin medical devices in Japan would be significantly higher than suggested by official statistics, approaching 60 percent for advanced medical technologies. U.S. medical device companies produce a wide variety of medical devices, but they are especially strong in sophisticated segments of the market such as pacemakers, advanced interventional cardiology products, orthopedic implants, laser surgical equipment, and advanced diagnostic imaging equipment. In the near term, the market is expected to increase in a measured fashion. Japan's aging population, continued demand for advanced medical technologies and the government of Japan's measures to promote healthcare industry will sustain growth.

Market Entry

Japan does not levy customs duties on medical devices. However, medical devices are heavily regulated under the Pharmaceutical and Medical Device Law (PMDL or PMD Act.). The Pharmaceutical Affairs Law (PAL) was amended and renamed the Pharmaceutical and Medical Devices Law (PMDL) on November 25, 2014. The PMDL will enable further improvements to the regulatory review process, including the establishment of a device-specific regulatory framework. Notable

Statistics

Capital: Tokyo
Population: 127,064,340 (2014)
GDP (USD): 4.901 trillion (2014)
Currency: Yen (JPY/¥)
Language: Japanese

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changes under the PMDL include expanding the scope of products eligible for third-party certification; allowing quality inspections to be conducted for product groupings as opposed to individual products; simplifying the manufacturer accreditation process; and making stand alone software a Class II device.

A Japanese company that intends to market a U.S. medical device needs to receive a “license for manufacturing/marketing business” (seizo hanbai gyo kyoka). The company holding this license is called a “Marketing Authorization Holder (MAH).” An MAH must be physically located in Japan. The MAH must obtain marketing approval (hanbai shonin) for each product. A U.S. manufacturer intending to manufacture medical devices in the United States and export them to Japan is required to be registered by the Pharmaceutical and Medical Device Agency (PMDA) as a “Registered Foreign Manufacturer” in the same way that a Japanese manufacturer is registered. Typically, an MAH can make a registration application on behalf of a U.S. manufacturer. A U.S. manufacturer that lacks a Japanese subsidiary can receive and maintain the marketing approval under its own name. However, the U.S. company will need to designate an MAH when applying for product approval. This Designated MAH (D-MAH) will have to assume the same responsibilities as an MAH. A D-MAH can be a regulatory consulting company or an importer/distributor that holds an MAH license. When a regulatory consultant is designated as an MAH, a U.S. company will need to have a Japanese distribution partner since a regulatory consulting company will not act as a distributor. If a U.S. company has a subsidiary in Japan, that subsidiary can become an MAH and then obtain the marketing approval for each product. If a U.S. company does not have a subsidiary in Japan, the company has three options to consider in order to conduct business in Japan:

- The U.S. company can ask their importer/distributor to obtain the marketing approval under the name of the importer/distributor. In this case, the importer/distributor will have complete control of the U.S. company's products when the products are marketed in Japan.
- The U.S. company can obtain the marketing approval under their own name by designating their importer/distributor as a D-MAH.
- The U.S. company can obtain the marketing approval under their own name via a neutral third party such as regulatory consulting companies that have a “license for manufacturing/marketing business” by designating them as a D-MAH.

Current Market Trends

The Japanese market for medical devices is large and established reaching USD 33.3 billion in 2013. The official figures for U.S. exports to Japan were limited to a 23 percent market share; however, according to the AMDD, an industry organization that represents the Japanese operations of 67 U.S.-based companies, approximately 60 percent of “new medical devices” approved in Japan were from AMDD member companies. Espicom Business Intelligence estimated that Japan's medical device market will exhibit a compound annual growth rate

(CAGR) of 3.8 percent from 2013 to 2018, and also the company estimated that all individual product categories should experience positive growth with the top performers being orthopedics and prosthetics (4.7 percent CAGR in local currency terms) and diagnostic imaging (3.9 percent).

Japan has a fast-aging demographic profile, with relatively prosperous seniors holding increasing expectations for improved quality of life in their late years. The Japanese health care system places increasing emphasis on improved treatment and health maintenance. This will generate further opportunity for the types of innovative solutions at which U.S. industry excels. In addition to sophisticated new medical devices, regenerative medicine and Health IT are subsectors that are particularly suited to meeting Japan's healthcare needs in the long run.

Regenerative Medicine: In November 2014, the PAL was amended and renamed to the Pharmaceutical and Medical Devices Law (PMDL). The PMDL will enable further improvements to the regulatory review process, including the establishment of a new product category for regenerative medicine products. The rapid approval system on regenerative medical products was introduced with the enforcement of the law, which raised Japan to the forefront of regenerative medicine. The Ministry of Economy, Trade and Industry (METI) released a research report on the market of regenerative medicine and related peripheral industries in February 2013: total market size of the clinical regenerative market in 2012 was estimated as 9.1 billion yen (USD 86.0 million at the rate of 105.74 yen to the dollar) which was about one-eighth of the U.S. market. METI's report projected that Japan's regenerative medicine market would grow in 2020 to 95.4 billion yen (USD 902.2 million) and to 10.31 trillion yen (USD 9.75 billion) in 2030, roughly one quarter of the U.S. market. METI also projected that the peripheral business such as cell culture and processing facilities, devices, reagents, logistics and other contract services was 17 billion yen (USD 160.7 million) in 2012, 95 billion yen (USD 898.4 million) in 2020, and 550 billion yen (USD 5.2 billion) in 2030.

Health IT: Japan ranked in the top position among 80 countries according to country case studies on healthcare IT metrics by the International Trade Administration of the U.S. Department of Commerce. For one such metric, Japan has the third highest GDP level globally (behind only the United States and China); a large Health IT market size (exceeding USD 1 billion); the oldest-skewing population distribution; a high concentration of population clustered in urban areas; a tech-friendly society; and very good Health IT infrastructure. All of these factors indicate that Health IT already has a good foundation in Japan, with the potential for more growth.

Main Competitors

The major product categories comprising Japan's domestic medical device production include: diagnostic imaging equipment; therapeutic and surgical equipment; biophenomena measuring and monitoring systems, home therapeutic equipment, dialyzers, and endoscopes. Japanese medical device companies maintain high market share in those product segments.

Top Japanese medical device companies, in terms of sales, include Terumo, NIPRO, Olympus Medical Systems, Toshiba Medical Systems, Hitachi Medico, Nihon Kodan, and Fukuda Denshi. U.S. medical device companies produce a wide variety of medical devices, but they are especially strong in sophisticated segments of the medical market such as pacemakers, advanced interventional cardiology products, orthopedic implants, laser surgical equipment, and advanced diagnostic imaging equipment. Most major U.S. and foreign medical device companies have either a Japan office or a Japanese partner. As such, new-to-market U.S. companies will face strong competition not only from Japanese companies but also from U.S. and multinational companies already in the market. In April 2009, Japan based U.S. medical device manufacturers launched a new association called the American Medical Devices and Diagnostics Manufacturers Association (AMDD, amdd.jp/en). The AMDD currently has more than 65 member companies.

Current Demand

Given Japan's aging population and the increasing number of patients with chronic and life-style diseases, medical devices that alleviate pain, complement lost functions, and improve the quality of life should show steady growth in demand. Also, the markets for in-home care devices, technologies, and health IT related products are expected to grow as the number of people in out-patient care increases. Due to stronger consumer health concerns, other promising growth areas include self-care and preventive care medical devices and products.

Registration Process

Japan's medical device classification system is based on the Japanese Medical Device Nomenclature (JMDN) codes which are different from U.S. and European classifications. Review processes for medical devices differ depending on the classification. Medical devices are classified by risk level into four classes (Class 1, Class 2, Class 3 and Class 4). Class 1 (lowest risk) is defined as general medical devices; Class 2 (relatively low risk) is defined as controlled medical devices; Class 3 (relatively high risk) and Class 4 (highest risk) are defined as specifically controlled devices. General medical devices can be marketed by submitting a notification to the Pharmaceutical and Medical Device Agency (PMDA). Controlled medical devices, with established certification standards, can be reviewed by third-party certification bodies. Controlled medical devices without certification standards and specifically controlled devices must be reviewed by PMDA and approved by MHLW.

Barriers

While the regulatory environment is expected to continue improving and the market for U.S. medical equipment in Japan remains strong, U.S. companies face challenges with pricing and reimbursement due to the GOJ's efforts to contain overall healthcare costs as a result of Japan's aging population. In the short term, the postponing of scheduled tax hikes from 8 percent in October 2015 to 10 percent in April 2017 has created a more challenging financial environment

as it generated additional revenues to fund healthcare expenditure, and also raised concerns with price revisions happening for three years in succession from 2016–18. Should potential price revisions under the proposed 2017 consumption tax raise take place, and the scheduled biennial price revisions occur in even-numbered fiscal years (2016 and 2018), this will lead to de facto annual revisions. Both U.S. and Japanese pharmaceutical industries are concerned that these changes could be used by advocates as ammunition to push for their proposal for annual revisions to continue from 2019.

Trade Events

MEDICAL Japan 2016

February 2016 • Osaka, Japan • medical-jpn.jp/en

Bio Asia International Conference

March 2016 • Tokyo, Japan • 10times.com/bio-asia-international

International Technical Exhibition of Medical Imaging (ITEM)

April 2016 • Yokohama, Japan • jira-net.or.jp/e

A comprehensive academic exhibition for the latest medical imaging systems and peripheral devices.

CPhi Japan

April 2016 • Tokyo, Japan • cphi.com/japan

MEDTEC Japan

April 2016 • Tokyo, Japan • medtecjapan.com/en

BIOftech Japan

May 2016 • Tokyo, Japan • bio-t.jp/en

INTERPHEX Japan

June 2016 • Tokyo, Japan • interphex.jp/en

International Modern Hospital Show (IMHS)

July 2016 • Tokyo, Japan

CEATEC Japan

October 2016 • Tokyo, Japan • www.ceatec.com/en

HOSPEX Japan (International Hospital Engineering Exhibition)

November 2016 • Tokyo, Japan • www.jma.or.jp/hospex/en



Jordan

Summary

Jordan is a regional leader in medical tourism. In 2014, the World Bank ranked Jordan as the leader in the Arab region and the fifth in the world as a medical tourism hub, boasting the latest technologies and highly-educated, well-trained doctors. Many Jordanian physicians have received some form of medical training in the United States, giving U.S. products good exposure.

- Ten percent of Jordan's GDP goes toward healthcare.
- Jordan's rate of healthcare expenditures is the third highest in the region. 106 hospitals serve Jordan's population and 250,000 patients from neighboring countries annually.
- The Ministry of Health has prohibited the import of used and refurbished medical devices into the Kingdom.
- Jordan requires USFDA, CE mark, or Japanese certification.
- The government plans to expand the "e-health initiative system" piloted in 2011 to public hospitals and beyond, including the storage, retrieval and updating of electronic health records of patients cared for by participating healthcare facilities.

Market Entry

Successful market entry strategies for Jordan have three common elements: understanding the market, selecting the optimal partner, and providing ongoing support to that partner. It is important to gain an understanding of the Jordanian context for a product or service, its competitors, standards, regulations, sales channels, and applications. Success in the market will require appointing a Jordanian distributor or establishing a local subsidiary, and setting-up a local sales presence. Typically, distributors for medical products will cover the entire country and/or region and some may also have an office in Dubai, Saudi Arabia or Iraq.

Statistics

Capital: Amman
Population: 6.6 million
GDP (USD): 33.68 billion (est. 2013)
Currency: Jordanian dinar (JOD)
Language: Arabic (official)

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U.S. companies are encouraged to appoint technically strong agents and distributors to sell their products and technologies in Jordan, and to participate in leading trade exhibitions, such as the “Arab Health” in Dubai, for market and product exposure. The U.S. Commercial Service (CS) offers programs to introduce U.S. products and technologies in Jordan. Performing due diligence on potential local partners is just as important as in the United States.

Parastatal companies purchase commodities through calls for international tenders. These are announced in the daily press. The Commercial Service of the U.S. Embassy in Amman reports most of these tenders to the U.S. Department of Commerce. U.S. companies must use a Jordanian agent to purchase tender documents from the issuing public sector entity.

In many cases, a U.S. company may not be able to provide the wide variety of products required in large tenders. However, a company can offer a bid by forming a consortium. Jordanian buyers prefer a single bid or an entire tender rather than having to piece together bids for each component. Public sector hospitals may request credit in their procurement tenders. While suppliers offering credit will certainly have a better chance of winning bids, sales without credit are sometimes made since other factors such as price, quality, and a delivery schedule may be of greater importance.

Ministry of Health tenders are issued by the General Supplies Department, while the University of Jordan, Royal Medical Services and the Ministry of Defense all release their own tenders. Tenders are published in the Jordan Times and the Middle East Economic Digest.

Current Market Trends

The USD 1 billion market is price sensitive and competitive. Jordan spends approximately 10 percent of its GDP on healthcare. Jordanians increasingly suffer from asthma; cancer; diabetes; obesity; heart stroke, vascular disease; osteoarthritis, rheumatoid arthritis; and osteoporosis. Opportunities exist for technologies that avert or reduce disability because of these diseases.

Some of the government initiative to reform the healthcare sector include:

- Renovating and adding medical diagnostic devices and therapeutic equipment
- Improving the quality of health care and hospital services
- Establishing a number of new hospitals
- Expanding and upgrading hospital infrastructure including the extension and modernization of pediatric facilities
- Developing and implementing health information systems and medical research
- Supporting the government hospitals’ accreditation projects
- Improving emergency services

Medical equipment

or medical equipment and services should increase during the next few years with the increase in the number of government and privately owned hospitals; new equipment for hospitals under construction; renovated equipment to replace existing equipment in functioning facilities; upgrading clinics and health care structures; expanding health insurance coverage; and shifting from older conventional methods to modern treatment methods. It should be mentioned that since 1998, the Ministry of Health has prohibited the import of used and refurbished medical devices into the Kingdom.

In the meantime, Jordan continues to make efforts, such as marketing campaigns and web promotions, to attract medical tourists from new destinations, including the former Soviet Union and Africa. In May 2015 Jordan held an international medical tourism congress aiming to develop new strategies to improve and expand the capacity of the private health sector while also seeking opportunities for growth from other markets. Regulatory policies are also being implemented to gain international quality accreditation to provide standardized protocols for global patients.

E-Health

The E-health care initiative is another key government program aiming to ensure the accountability of the health care system. The e-health system will operate the storage, retrieval and updating of the electronic health records of patients cared for by all the participating healthcare facilities in Jordan. The government began a pilot project of the system in 2011 and will expand it to the entire health care system, starting with public hospitals.

Main Competitors

Imports supply approximately 80 percent of Jordan's demand for medical equipment. Key suppliers include the United States, the European Union, Germany, Switzerland, and Japan. Many suppliers in the Jordanian industry are distributors. The major U.S. medical companies represented in Jordan (either through local representatives or subsidiary offices) include GE Ultrasound, Philips, Johnson & Johnson Medical, and Medtronic.. U.S. companies may experience strong competition from other U.S. companies or multinationals already in the market.

Current Demand

Importers seek to source cost-effective and innovative products that will improve patient outcomes and reduce healthcare costs. Opportunities exist for products that provide a significant improvement in clinical outcomes, and product with clearly differentiated capabilities.

Government healthcare policies and public health influence the volume and pricing of healthcare products and services. Both the public and private sectors provide healthcare in Jordan. Healthcare expenditure in 2014 is expected to reach USD 3.21 billion.

Medical tourism generates over USD 1.2 billion in revenues annually. In 2014, 250,000 patients traveled to Jordan for medical treatment, and Jordan expects to reach 300,000 medical tourists in 2018, with potential revenues of USD 1.5 billion. Jordan's rate of healthcare expenditures is the third highest in the region. 106 hospitals serve Jordan's population and around 250,000 patients from neighboring countries annually.

The Jordanian medical device market is projected to grow at an above average pace of 9.3 percent per year until 2018, from an estimated USD 243.7 million in 2015 to USD 380.9 million in 2018. The overall market size and per capita spending will remain comparatively small in global terms. The key driver of growth remains medical tourism, for which Jordan is the number one destination in the region.

The number of new hospitals, both private and public, is expected to grow, as is the demand for medical equipment and pharmaceuticals for the following reasons: equipment will be needed for newly constructed hospitals and for clinics and hospitals that are being renovated.

There is a need in the next five years for new hospitals in Jordan, (focusing on the cities of Amman, Zarqa, and Irbid). This new hospital construction will trigger demand for both professional services and medical products:

Best prospects include:

- | | | |
|---|--|---|
| <ul style="list-style-type: none">• Consulting in hospital administration• Quality control and certification standards• Laboratory and hospital administration software;• Diagnostic imaging equipment (CT, MRI)• Laboratory reagents and diagnostics• Testing equipment | <ul style="list-style-type: none">• Cardiology and kidney dialysis equipment• Hospital furniture• Equipment and supplies for plastic surgery• Medical surgical sterilizers• Medical x-ray, alpha, beta, gamma ray equipment• Orthopedic and prosthetic appliances | <ul style="list-style-type: none">• Clinical lab diagnostic equipment and clinical laboratory equipment• Organ transplant equipment• Ophthalmology• Neurosurgery• Oncology• Consumables for clinical laboratories, i.e. tubes/ glass |
|---|--|---|

E-health best prospects include:

- Healthcare management systems
- Software modules for specific fields and applications (radiology, imaging, etc.)
- Integrated medical insurance solutions
- Medical devices and equipment
- Customer relations management
- Mobile healthcare applications
- Online medical content providers

Registration Process

The Ministry of Health sets technical rules and specifications applicable to all medical equipment to ensure that all products being sold to Jordanian end users meet the requirements of safety and quality. In Jordan, public sector tenders do not require regulatory review if the product has been authorized for marketing in the US, Europe or Japan. Other specifications are stipulated in the tender terms on a case-by-case basis.

Medical equipment procured by the public sector is tested either by the beneficiary itself (i.e. Ministry of Health, Royal Medical Services, etc.) or the Royal Scientific Society. This testing is not applicable to medical equipment procured by the private sector, which is not subject to any testing procedures.

Trade Events

Arab Health

January 25–28, 2016 • Dubai, UAE

International Dental Conference and Arab Dental Exhibition

February 2–4, 2016 • Dubai, UAE

Medical Tourism Conference

May 2016 • Amman, Jordan



Kenya

Summary

Kenya is the most developed economy in Eastern Africa and also the economic, commercial, financial and logistical hub of the entire region. Kenya's population is comprised of a large number of young (almost 70 percent of the population is under the age of 35) well-educated English-speaking, and multi-lingual professionals, and a strong entrepreneurial tradition. Kenya's healthcare markets are one of the fastest growing on the African continent and are expected to register strong double-digit growth with medical devices at 10 percent annually through 2014–18, clinical chemistry and diagnostic products at 15–25 percent annually and pharmaceuticals at 14–16 percent annually over the same period.

Market Entry

The Kenyan healthcare market relies almost entirely on imports of medical devices, pharmaceuticals (at least 70–80 percent), dental products, laboratory equipment, healthcare IT, clinical chemistry and diagnostics. Kenya is the key logistical conduit into East Africa and many foreign suppliers operating here do business under their own name to manage penetration into the larger, regional market. Success on the Kenyan market requires that local presence and after-sales support be considered via a local representative, for example an agent or distributor, or a joint venture partner or franchisee.

Current Market Trends


U.S. healthcare suppliers are in an excellent position to increase their market share in Kenya due to U.S. technical competitiveness in assuring quality and reliability of U.S. healthcare products although price is occasionally an issue. Leading private sector hospitals are very active in modernizing their medical equipment inventories, while public sector hospitals are constantly re-equipping with improved budgetary allocations. Additionally, the passage of a new constitution

Statistics

Capital: Nairobi
Population: 45 million
GDP (USD): 61 billion
Currency: Shilling (KES)
Language: English, Swahili

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in August 2010 established 47 county governments, each of which is responsible for providing health facilities and services. These county governments, managed by a county governor, receive at least 15 per cent of their annual funding from the central government. Additionally, through a USD 400 million Managed Equipment Services (MES) contract/leasing program that the Ministry of Health (MoH) launched in February 2015, two public hospitals in each of the 47 counties will be fully equipped with state-of-the-art medical equipment, over a 12-month period.

Main Competitors

Major suppliers of healthcare products include India, China, United States, Germany, Belgium, Switzerland, Belgium, South Africa, Italy and Japan. Leading medical companies that sell product in Kenya include GlaxoSmithKline, Roche, Sanofi Aventis, Pfizer, AstraZeneca, Philips, Siemens, Novartis, Abbot, GE Medical, Becton Dickinson, Drager, and Welch Allyn.

Current Demand

Past government tenders for medical equipment indicate requirements for basic equipment such as anesthetic machines, anesthetic trolleys, hydraulic operating tables, delivery beds, infant incubators, mortuary trolleys, hydraulic operating tables, mercurial sphygmomanometers, and oxygen flow meters among others. Best prospects for electro-medical devices include: CT scanners, ultrasound units, X-ray equipment, mammography units, MRI equipment, angiography, endoscopy, biochemistry, hematology, and immunology systems. Best prospects for clinical chemistry and diagnostics are in serology/hematology, immunochemistry, urinalysis, electrolytes analysis, diabetes testing and cardiac markers while those for pharmaceuticals are in affordable patented and generic drugs used to manage HIV/AIDS and associated opportunistic infections, malaria, cancer, diabetes and hypertension. Used and refurbished medical devices have an open market in Kenya so long as they conform to national standards.

Registration Process

The Pharmacy and Poisons Board (PPB) regulates the practice of pharmacy and the manufacture and trade in pharmaceuticals and medical devices in Kenya.

To register a pharmaceutical product, please visit pharmacyboardkenya.org/index.php?id=10.

To register a medical device, please visit pharmacyboardkenya.org/index.php?id=13.

Diagnostic kits and reagents that specifically test for sexually transmitted infections (including HIV/AIDS and hepatitis) are required to be evaluated by the National Public Health Laboratories to ascertain the quality and reliability of these products. Product evaluations typically involve 400 tests at a cost of about USD 1,000.

Barriers

In September 2005, the Kenya Bureau of Standards (KEBS) implemented the Pre-export Verification of Conformity (PVoC) program, a conformity assessment and verification procedure applied to specific “Import Regulated Products” from exporting countries to ensure their compliance with the applicable Kenyan technical regulations and mandatory standards or approved equivalents (international standards and national standards). KEBS requires that all consignments of regulated products entering Kenya must obtain a Certificate of Conformity issued by an appointed PVoC country agent, a mandatory customs clearance document in Kenya; consignments of regulated products arriving at Kenyan Customs Points of Entry without this document will be subject to delays and possibly denial of admission into Kenya.

Trade Events

Medic East Africa

September 1–3, 2015 • Nairobi, Kenya • mediceastafrica.com

MEDEXPO AFRICA

November 17–19, 2016 • Nairobi, Kenya • expogr.com/kenyamed

Korea, Republic of

Market Entry

Medical devices are distributed mainly through local distributors. A local distributor may directly cover the whole country on an exclusive basis or a master distributor may contract with other regional sub-dealers for sales nationwide.

Sales leads for medical devices in Korea are normally created through steady communication with local subsidiaries or between distributors/commission agents and physicians on an individual basis. Local representatives call on physicians frequently and provide information on products to maintain good relationships.

One reliable distributor to cover the country on an exclusive basis is highly recommended for the Korean market since Korea is a geographically small country, and major users for high end medical devices are limited to general hospitals and university hospitals. More than one distributor often confuses clients in terms of representation and prices and diminishes the reliability of the foreign supplier.

Current Market Trends

In 2014, the top 10 medical devices imported into Korea included:

- Stents
- Soft contact lenses
- Sight corrective ophthalmic lenses
- Dialyzers for hemodialysis
- Knee joint prostheses
- MRI devices
- Analyzing products, Chemiluminescence immunoassay (CLIA)
- Intravascular catheters
- CT systems
- IVD reagents for clinical immunochemistry

Main Competitors

Korea depends on high-end medical devices from the U.S., EU, and Japan, to supply about 60 percent of total market demand. Currently, the United States

Statistics

Capital: Seoul
Population: 49.04 million (2014)
GDP (USD): 1.45 trillion (2014)
Currency: S. Korean won (KRW)
Language: Korean

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has largest import market share in Korea, followed by the EU and Japan. Korean companies manufacture comparatively lower-end (mid-technology) medical devices.

Current Demand

In 2015, total imports of medical devices were estimated at USD 3.2 billion, with U.S. imports totaling over USD 1.4 billion. The U.S. market share represents approximately 40 percent of the import market. Market demand for foreign advanced and innovative medical devices is estimated to have experienced slow growth in 2015 since Korea is facing budget control challenge under its National Health Insurance system.

Registration Process

All medical devices are required to obtain marketing clearance from the Ministry of Food and Drug Safety (MFDS) before they are manufactured in or imported into Korea. Currently, medical devices are classified into four categories in Korea depending upon technical attributes and product use. MFDS requires pre-market notification for class I devices and pre-market approval for class II, III, and IV devices. Class III and IV devices must pass the most stringent technical review by MFDS with authorized labs to prove their safety and effectiveness. Since MFDS issues product licenses only to locally based companies, all foreign suppliers must submit required documentation and receive necessary approvals through their Korean importers, or U.S. supplier's corporation located in Korea.

The lead-time for approval is typically 6–12 months, including company-working time for preparing applications. Although MFDS indicates its requirements for the approval in relevant regulations, specific detailed requirements could be different according to each product item. Thus, U.S. companies should closely work with their Korean importers to determine MFDS's requirements on a case-by-case basis to obtain approvals.

Barriers

National Health Insurance Program and Reimbursement Pricing

Korea has compulsory National Health Insurance (NHI) system for 50 million citizens. The NHI system was introduced in 1977 and covered entire population by 1989. The Korean government administers funds, coverage, coding, payment and pricing.

Tariffs

Due to the Korea-US Free Trade Agreement (KORUS FTA) implemented on March 15, 2012, approximately 85–90 percent of imported medical devices in Korea received duty-free treatment within one year, and tariffs on the rest will be eliminated by 2018.

Kuwait

Summary

In February 2010, Kuwaiti Parliament approved a USD 110 billion (KWD 31 billion) National Development Plan (NDI), stretching to 2035, based on a series of five 5-year plans, which aim to convert Kuwait into a trade and financial hub of the region. The plan introduces ideas and laws to fund the development projects and to provide support to various sectors, including building a stronger healthcare system through the promotion of healthy lifestyles and behavior and enhancing the healthcare infrastructure.

Kuwait's public healthcare sector accounts for more than 80 percent of the healthcare spending in the country. Currently, Kuwait's Ministry of Health is the owner, operator, regulator, and financier of the vast majority of healthcare services rendered, pharmaceuticals purchased, and medical equipment acquired in the country. The government of Kuwait is currently operating 15 general and specialized hospitals with the private sector expected to grow moderately in the coming years. Private companies are estimated to take a share of 15–20 percent of healthcare spending.

In 2012, the Ministry of Health and the Ministry of Public Works announced a USD 4.42 billion (KWD 1.250 billion) project to replace and/or expand nine operating hospitals (five general hospitals and four specialized hospitals), which will add an additional 5,400 beds, 150 operating rooms, and 500 outpatient clinics. In addition, the USD 1.1 billion (KWD 304 million) Sheikh Jaber Al-Ahmed Al-Sabah Hospital, which is expected to be completed by end of 2014, will add another 1,200 beds. Currently the Ministry of Health hospital bed capacity stands at nearly 6,000 hospital beds.

Between 1995 and 2013, Kuwait's Ministry of Health operating budget has increased from USD 895 million (KWD 253 million) to USD 4.5 billion (KWD 1,294 million). In addition, during the same period, the Ministry of Health per capita expenditure has increased from USD 456 (KWD 129) to USD 1,175 (KWD 332).

Statistics

Capital: Kuwait City
Population: 4.1 million (2015)
GDP (USD): 181.0 billion (est. 2015)
Currency: Kuwaiti Dinar (KWD)
Language: Arabic (official), English

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Approximately 50 percent of Kuwait's Ministry of Health operating budget is geared towards salaries and benefits. If the Compounded Annual Growth Rate (CAGR) stabilized at 7 percent, Kuwait's Ministry of Health operating budget would reach about USD 18 billion (KWD 5 billion), by 2030.

Although the population is young on average, the World Health Organization (WHO) indicated that Kuwait is ranked 13th in the world for obesity and seventh for diabetes. In addition, WHO's metabolic risk factor for both male and female Kuwaiti nationals indicates that 78.8 percent suffer from overweight, 42 percent suffer from obesity, and 54 percent suffer from raised cholesterol

Market Entry

The GCC has a 5 percent flat rate tax on imports. Kuwait corporate income taxes for foreign corporations ranged from 15–55 percent, but have been changed to a flat 15 percent as of 2008. To be successful in the Kuwaiti market, U.S. companies often identify, develop and support a local agent, representative, or account executive to manage their marketing strategy. Some companies find having a Kuwaiti partner rather than an agent a preferable approach, in part due to the local tax law. Prior success in other GCC countries is helpful but companies rely on local experience and knowledge to conduct their business in these markets. Knowing regulations and the general business framework is a difficult task without the support of a competent local agent or business partner. U.S. companies should seek this type of business relationship and understand that the best representatives are those who are already active in their particular sector with cultivated contacts.

In summary, selecting the appropriate agent who will work for you is the single most important step a U.S. exporter can take in Kuwait. Getting competent local legal counsel to craft an agreement that protects your company from future liability is also a key. The best local partners are those who share both the risk and profit with their U.S. partners.

Main Competitors

The Kuwait market is totally dependent on imports for medical devices; while U.S. suppliers enjoy some advantages, including competitive prices, language, and exchange rate. European suppliers are aggressively gaining market share with their close proximity to the market and perceived high level of customer support.

Current Market Trends

The healthcare sector is moving toward becoming a regulated market sector through reform initiatives that are being implemented. The privatization initiative involves broadening public-private partnerships and giving the private sector a growing role in the provision of healthcare services. Recently, public healthcare centers began referring patients to private medical care providers for services like IVF treatment and physiotherapy. Such soaring healthcare spending

reflects the GOK's priority to improve the quality of life for both citizens and expatriates and to treat more Kuwaiti patient's in-country.

Current Demand

Currently, Kuwait has two hospital beds per 1,000 people, an undersupply of serious concern given the population growth and the growing disease burden.

Registration Process

Kuwait's Ministry of Health requires the following for product registration:

- Free Sale Certificate from the concern health authority of origin to be legalized by Kuwait Embassy. This certificate should mention the trade name of the product, its volumes or weight, and it should state the product is allowed to be sold freely in the country of origin.
- Certificate of composition (exact percentages) signed and sealed by the manufacturer.
- Certificate of analysis signed and stamped by manufacturer.
- Samples of each product to be tested.
- A Kuwaiti importer

Barriers

The need for a Kuwaiti agent, distributor, or partner tends to add to the cost of selling goods in Kuwait.

Imports to Kuwait require three certified and legal copies of the commercial invoice, three copies of the transport documents and two copies of the certificate of origin. The certificate of origin must describe the place of origin of the goods, the full name of the manufacturing plant or producer and the full name of the freight forwarder. It must also show gross and net weight, the trademark shown in the manifest, value, type of packaging and means of transport. The certificate must be certified by the Chamber of Commerce in the exporter country and most of the time by Kuwait Embassy or any one of the GCC states mission in the absence of a Kuwaiti mission.

Kuwait Customs is strict and most of the Kuwaiti importers/companies know the best ways to get the imported items faster to the country.

Trade Events

Most Kuwaiti companies attend Arab Health in Dubai, UAE, as well as shows held in Germany and the United States.



Libya

Summary

Libya's Medical sector is one of the public sectors that suffered the most during the previous totalitarian regime. Libya's hospitals and clinics largely do not meet international standards. Libyans with sufficient resources travel to Tunisia, Jordan, or Europe for anything but the most routine medical care, a trend that has led to the establishment of a 100+ mile "medical services alley" on the Tunisian side of the border. The Ministry of Health establishes regulations regarding the Libyan health sector and is responsible for issues related to public health, precautionary health, therapeutic medicine, medical institutions, pharmaceuticals, control of the circulation of drugs and medical practice and related professions. Decree 38 of 2012 placed central, special, general and rural hospitals under the direct regulation of the Ministry of Health. According to Ministry of Economy Decree 103 of 2012, foreign companies with necessary experience are permitted to open independent branch offices and execute the installation, commissioning, and maintenance of medical equipment and/or the management of hospitals and medical institutions. Generally, importation of medical equipment and supplies into Libya is allowed so long as the manufacturer is register with the Ministry of Health.


Libya is a welfare country where health and education are free and provide universal coverage. There have been impressive improvements in health and education standards over the past decennia. Health services were badly disrupted in Libya during the conflict in 2011, and access to health services remains problematic, particularly for many vulnerable populations in need of mental health or psychosocial support, the displaced and mobile populations, the war wounded in need of treatment and rehabilitation, the victims of gender based violence, pregnant women left without antenatal, delivery and post-partum maternity services in nearby non-functional.

Statistics

Capital: Tripoli
Population: 6.5 million
GDP (USD): 70 billion
Currency: Libyan dinar (LYD)
Language: Arabic

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During the crisis WHO has played a key role in coordinating, mobilizing and optimizing health actions to address the immediate needs as well as to provide technical assistance and guidance. In the post-conflict phase WHO is expected to play a major role in coordination with essential stakeholders and partners in the restoration and development of the health system in order to resume and maintain provision of quality health services to the Libyan population.

Market Entry

Successful market entry strategies for Libya have three common elements: understanding the market, selecting the optimal partner, and providing ongoing support to that partner. It is important to gain an understanding of the Libyan context for a product or service, its competitors, standards, regulations, sales channels, and applications. Success in the market will require appointing a Libyan distributor or establishing a local subsidiary, and setting-up a local sales presence. Typically, distributors for medical products will cover the entire country.

U.S. companies are encouraged to appoint technically strong agents and distributors to sell their products and technologies in Libya, and to participate in leading trade exhibitions, such as the “Arab Health” in Dubai, for market and product exposure. The U.S. Commercial Service (CS) offers programs to introduce U.S. products and technologies in Libya. Performing due diligence on potential local partners is just as important as in the United States.

In many cases, a U.S. company may not be able to provide the wide variety of products required in large tenders. However, a company can offer a bid by forming a consortium. Libyan Ministry of Health prefers a single bid for an entire tender rather than having to piece together bids for each component. Public sector hospitals may request credit in their procurement tenders. While suppliers offering credit will certainly have a better chance of winning bids, sales without credit are sometimes made since other factors such as price, quality, and a delivery schedule may be of greater importance.

The five-year National Development Plan (2008–12) aims to modernize Libya’s essential infrastructure through international partnerships. About USD 35 billion has been allocated, with particular focus on the construction and equipping of healthcare institutions.

Existing major hospitals are also being converted into educational institutions, partnering with and managed by an already established international hospital that will provide training in hospital management and modern healthcare systems. More than 20 hospitals have already been targeted for this purpose.

Integral to this program is the creation of a national network of Primary Healthcare (GP) Surgeries and Polyclinics. The development of primary care in Libya is essential, if only to take away some of the workload from the country’s hospitals which are too commonly used as walk-in clinics by Libyans. The Tripoli Medical Center, for example, a specialized tertiary care

and medical student training hospital, estimates that up to 40 per cent of its resources are currently spent providing basic primary care services to local people.

Plans are also in place to build and refurbish secondary and tertiary care institutions (i.e. hospitals and specialist care clinics); and unlike the “false start” of 2002, the necessary funds and the political will now seem to be in place for this ambitious program to succeed—a situation which also promises to create lucrative partnership opportunities in large-scale healthcare projects.

The Ministry aim is to employ comparable procurement models to those developed around the world over the past decade in developing health services in Libya. The widespread adoption of PPP and PFI-style projects (as well as more focused investment schemes similar to NHS LIFT for improving and developing frontline primary and community care facilities) are seen as key to the future of the Libyan healthcare system.

The market for medical and pharmaceutical products offers the most clearly available opportunities for companies in Libya’s healthcare sector: “There are excellent doctors in Libya; however the hospitals are in dire need of modern equipment, technology, healthcare products and drugs.”

In the absence of local production, imports are growing rapidly. At the end of 2006, (the most recent figures available) the total value of imports of drugs and medical consumables was estimated at LYD 560 million per year, around 60 per cent for pharmaceutical products, and 40 per cent for medical supplies.

Government agencies are the main buyers, though organizations such as the Red Crescent and the increasing number of private clinics are increasingly active in the country. Imports were a state monopoly but, since the opening and privatization of this market, new import licenses have been granted to certain operators to supply pharmacies and private clinics.

The reorganization of the public sector currently covers around 60 per cent of total demand. Companies that want to take part in public procurements or distribute products on the market through a local agent must be registered with the Food and Drug Control Centre.

Tenders generally take place in spring for public procurement, but according to some companies active in the market, these processes have, in the past, tended to be anything but predictable. However, since the centralization of Libya’s healthcare administration in March 2006, these processes have become more standardized, predictable and workable.

Current Market Trends

Libya spends approximately 10 percent of its GDP on healthcare. Libyans increasingly suffer from heart stroke; cancer; diabetes; rheumatoid arthritis; asthma; obesity; vascular disease; osteoarthritis, and osteoporosis. Opportunities exist for technologies that avert or reduce disability because of these diseases.

Some of the government's healthcare reforms include:

- Supporting the government hospitals' accreditation projects
- Renovating and adding medical diagnostic devices and therapeutic equipment
- Developing and implementing health information systems and research
- Establishing a number of new hospitals
- Improving the quality of health care and hospital services
- Expanding and upgrading hospital infrastructure including the extension and modernization of pediatric facilities
- Improving emergency services

Main Competitors

Libyan suppliers are mainly European, with the UK alongside the Italians, Swiss, Germans and French at the forefront of the market.

Current Demand

- Hospital administration consulting
- Surgical sterilizers
- Radiological equipment
- Clinical lab and diagnostic equipment
- Laboratory and hospital administration software
- Software modules for specific fields and applications (radiology, imaging, etc.)
- Integrated medical insurance solutions
- Medical devices and equipment
- Customer relations management
- Healthcare management systems
- Organ transplant equipment
- Quality control and certification standards
- Diagnostic imaging equipment—CT, MRI, and PET scanners
- Laboratory reagents and diagnostics
- Testing equipment
- Cardiology and kidney dialysis equipment and
- Hospital construction
- Project planning
- Equipment and supplies
- Orthopedic and prosthetic appliances
- Mobile healthcare
- Training

Registration Process

The Ministry of Health sets technical rules and specifications applicable to all medical equipment to ensure that all products being sold to Libyan end users meet the requirements of safety and quality.

Medical equipment procured by the public sector is tested either by the beneficiary itself (i.e. Ministry of Health). This testing is not applicable to medical equipment procured by the private sector, which is not subject to any testing procedures.

Macedonia

Summary

Macedonia continues to undertake a series of major health sector reforms.

The purpose of these reforms is to enable access to high quality primary care that is financially sustained through more appropriate roles for public and private healthcare institutions and more efficient allocation of resources.

In order to achieve these goals of health sector reform, the Ministry of Health of the government of the Republic of Macedonia has set five core policy areas to improve: health expenditures; health revenues; provider payment mechanisms; information systems; and advocacy and public awareness strategies.

The main contributors to health system reform in Macedonia, other than World Health Organization (WHO), are the World Bank, UN agencies, and the government. Their broad based efforts focus on several components: health finance reform and management; basic health services; fostering public-private partnership in health sector; and pharmaceutical policy.

In parallel to health sector restructuring efforts, the health sector management project has continued to be a particular focus. The objectives of this project are to upgrade the Ministry of Health, the Health Insurance Fund, and the local health facilities capacity to formulate and effectively implement health policies, health insurance, financial management and contracting of providers, as well as to develop and implement efficient schemes for the restructuring of hospital services, with an emphasis on developing day care services and shifting to quality primary care.

The disease prevalence pattern is similar to other European countries, with cardiovascular and circulatory disease, neoplasms, metabolic and nutritional diseases, and respiratory diseases as the most prominent causes of morbidity and mortality. Diseases like HIV and TB are less prevalent.

Statistics

Capital: Skopje
Population: 2 million
GDP (USD): 11.324 billion (2014)
Currency: Macedonian Denar (MKD)
Language: Macedonian, Albanian

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In the last several years, Macedonia has continued to spend between 1.0 to 1.3 percent of its GDP on the healthcare sector.

Market Entry

There are no legal barriers to foreign companies entering Macedonia. However, challenges to doing business in Macedonia remain, including the country's weak judicial system and significant levels of corruption. According to import regulations, all medical equipment entering Macedonia is free of import duties, but still subject to 18 percent value added tax (VAT). Exceptions are applied to the accessories and spare parts which are subject to 8, 10, and 15 percent customs import duty. The CE marking is mandatory, as is compliance with ISO standards.

Main Competitors

European companies remain the main competitors to U.S.-produced medical equipment and pharmacies. Consumers in Macedonia are highly receptive to U.S. products, but they are also very sensitive to prices. Siemens, Philips, Hitachi, and Toshiba are active in the market.

Current Demand

Macedonia's healthcare sector remains in need of medical materials, including pharmaceutical drugs, disposable products, and medical equipment. Invasive and non-invasive surgery equipment, cardiology equipment, EKG and ultrasound, defibrillators, vascular stents, pacemakers, oncology equipment, urology, laboratory and testing equipment, remain in high demand as do computer tomography imaging systems, magnetic resonance imaging, and sophisticated digitalized x-ray equipment.

Registration Process

In order to harmonize country's legislation with European Commission recommendations, the Assembly of the Republic of Macedonia has adopted extensive amendments to the Law on Medicinal Products and Medical Devices that came into force on February 1, 2012.

According to this law, all medical devices marketed in Macedonia must be labeled according with the provisions of this law on the outer and inner packing in Macedonian and English language, and must enclose instructions for use.

A packing of medical devices must contain, at least, the following: information on the manufacturer, supplier, information necessary for the identification of the medical device and contents of the packing, different labels like sterile, custom-made, single use, for clinical trials, identification code, expiry period, storage conditions, a special method of use, warnings or precautions, purpose and other information related to proper use of the device and public health protection.

The medical devices and pharmaceutical products require registration at The Bureau for Medicine and Medical Devices, who is the administrative body regulating the Law of Medicinal Products and Medical Devices.

Barriers

There are no significant trade barriers or limitations on U.S. produced medical devices.

Trade Events

No specialized medical and healthcare trade show scheduled in 2016.

Resources

- Ministry of Health of Macedonia, moh.gov.mk
- Health Insurance Fund of Macedonia, www.fzo.org.mk



Malaysia

Summary

Malaysia's national healthcare expenditure historically is around 4–5 percent of GDP. In 2014, the Malaysian government set aside approximately USD 5.83 billion (MYR 22.16 billion, forex USD 1=MYR 3.8), or 8.4 percent of the yearly national budget for public healthcare. Out of this allocation, 7.5 percent is assigned for development purposes. Comparing public and private hospital expenditure, the public hospitals expenditure is about 65 percent while the private sector is around 35 percent. The number of hospital beds for both public and private healthcare combined has increased from 55,180 in 2010 to 58,530 in 2014. Public hospital beds accounted for 75 percent of total hospital beds in 2014.

Total two-way trade for Malaysia's medical device industry for 2014 is USD 1.98 billion. Malaysian imports of medical, surgical, dental and veterinary science instruments and devices amounted to USD 735 million. Singapore (27 percent) is the highest supplier to Malaysia. This is followed by the United States (19 percent), Germany (13 percent), Japan (8 percent), China (7 percent), and South Korea (3 percent). Overall, Malaysian medical device imports increased 8 percent over 2013. It is also worthwhile to note that Singapore is a major trans-shipment point for the Association of South East Asian Nations (ASEAN) region.

Exports for the same category of medical instruments and devices from Malaysia increased 24 percent to USD 1.24 billion in 2014. Top export destinations for Malaysia in this sector are the United States (43 percent), Germany (14 percent), Japan (22 percent), and Singapore (12 percent). It is also interesting to note a marked increase in total trade between Malaysia and the Netherlands. Total bilateral trade between Malaysia and Netherlands is USD 60 million for 2014, an increase of 143 percent over 2013.


The government of Malaysia designated the Medical Device Industries sector as high growth potential in its next five year strategic economic plan (2016–20), also known as the 11th Malaysian Plan (11MP). According to the Malaysian Ministry of

Statistics

Capital: Kuala Lumpur
Population: 29.9 million
GDP (USD): 326.93 billion (2014)
Currency: Ringgit Malaysia (MYR)
Language: Bahasa Malaysia

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International Trade and Industry, from 2010–14, foreign medical device industry investments into Malaysia totaled MYR 11 billion (USD 2.9 billion), while domestic investments were MYR 1.2 billion (USD 316 million).

Improving and achieving universal access to quality healthcare will be the focus of the Malaysian government for the next five years. The major thrusts will be in improving healthcare quality to underserved populations, as well as ensuring efficient and effective expansion of the healthcare delivery system. In addition to upgrading healthcare facilities, a government priority is to reduce communicable and non-communicable diseases (CD and NCD). E-Health Information and Communications Technology (ICT) strategy will be implemented concurrently to track and support these measures.

The government is pushing intensified private sector collaboration between the Ministry of Health (MOH), corporate social responsibility (CSR) programs, and Non-Governmental Organizations (NGOs); cross collaboration with industry groups, higher education, and research institutions will also be emphasized.

Market Entry

Many exporters designate a Malaysian-based trading company as their local sales agent responsible for handling customs clearance of imported goods, for dealing with established wholesalers and/or retailers, for marketing the product directly to major corporations or the government, and for handling after-sales service. In some cases, especially when selling to the government, a Malaysian Bumiputra status distributor is required. The term Bumiputra refers to a Malaysian of Malay or indigenous racial origin.

The passing of Act 737 and Medical Device Regulations 2012 has changed the regulatory framework for Malaysia. Industry players intending to export to Malaysia now need to register their medical devices with the Malaysian Medical Device Authority. Pharmaceutical and health supplements registration is with the National Pharmaceutical Control Bureau.

Current Market Trends

Increasingly, more Malaysians are taking the approach of wellness and disease prevention rather than treatment. Food and vitamin supplements are seen as preventive measures towards maintaining optimal health. Basic vitamin and pro-vitamins, as well as natural and organic supplements, are gaining popularity. The U.S. is the largest supplier of healthcare supplements to Malaysia. U.S. brands are both trusted and well received by local consumers.

As for dental market trends, we are seeing subspecialties in the area of orthodontics, implant and esthetic procedures increasingly being offered in private dental clinics. The United State is one of the leading suppliers of orthodontics products in Malaysia.

Private healthcare services in Malaysia are predominantly used by the upper-middle to affluent segment of the population. As per capita GDP rises, demand for private healthcare consumption is expected to increase in tandem. Health screening is increasingly popular. Medical aesthetics procedures are also gaining ground in Malaysia.

Similar to other increasingly affluent countries, NCDs such as diabetes, high-blood pressure, cardiovascular disease, oncology cases, and obesity are on the rise in Malaysia. The major vector-borne disease that Malaysia is having a difficult time containing is Dengue Fever. Tuberculosis is an increasingly infectious disease in Malaysia, with high mortality rate. Although Malaysia has been BCG-vaccinating its citizens from birth, and boosters vaccination administered for school going children for many decades, we are seeing a resurgence in TB cases. The main cause is the influx of migrant workers into the country. Hand, Foot and Mouth Disease is also prevalent, but there is no associated mortality with this disease in Malaysia. HIV/AIDS is the third main infectious disease in Malaysia with high mortality rate.

Main Competitors

The main competitors for the United States in the Malaysian market are the EU countries of Germany, the Netherlands, United Kingdom, and France. Japan, China/Hong Kong, and South Korea have a strong presence in the Malaysian market as well. As noted above, statistical data show that the Netherlands made strong inroads into the Malaysian market in 2014 for the medical device sector, with 143 percent total bilateral trade growth over 2013.


Singapore (#1 for imports into Malaysia, #4 for exports) is the sole ASEAN country enjoying strong trade relations with Malaysia on the medical device front. The other strong neighboring ASEAN trade partners in Malaysia's top 15 ranking are Vietnam (#11 for imports, #12 for exports), Thailand (#13 for imports) and Indonesia (#11 for exports).

In the pharmaceutical sector, local players are making increasingly strong progress in supplying the domestic market with generics and OTC drugs. These drugs are usually off-patent with no/minimal Research and development efforts.

Current Demand

Consolidation is the key word for public healthcare resources and facilities. The government of Malaysia will implement a hospital cluster concept in select locations. Hospitals within a similar geographic region will serve as one unit sharing assets, amenities and human resources. Additionally, existing healthcare facilities and assets will also be upgraded. Healthcare services to the rural and remote areas will be expanded via mobile healthcare teams and flying doctor services.

Implementation of the e-Health strategy will include incorporating existing ICT system into one system-wide module. This will hopefully improve health data management, and support research and development and commercialization initiatives.



Pre-hospital care such as ambulance services, and accidents and emergencies services will also be a key focal area. Ideally, collaboration between private sector and NGO ambulance service providers will improve response time and better resource utilization.

In the private healthcare front, there is huge upside. Demand for private healthcare has been increasing exponentially due to its speedy service delivery and quality healthcare. In 2013, private hospital outpatient attendance was 6.8 percent of overall outpatient care provided in-country. However, private hospitals command 32.2 percent of total hospital admissions. In 2013, approximately 25 percent of the doctors, 38 percent of dentists, and 33 percent pharmacists were in private practice.

Registration Process

The Malaysian Medical Device Act 2012 (Act 737) has been approved by the MOH and is published in the Gazette on Dec 31, 2012. The Regulations specify requirements and procedures to medical device registration, conformity assessment body (CAB) registration, establishment licensing, export permit and appeal.

The Regulations went into force on July 1, 2013. A transition period of two years for medical device registration and one year for establishment licensing will be given to the industry before it is fully enforced. The Medical Device (Exemption) Order 2015 has extended the transition period of medical devices registration for another year, ending June 30, 2016.

Thereafter, all medical device manufacturers in Malaysia will need to register their medical devices with the Medical Device Authority. Importers and distributors will also need to obtain an establishment license to import and distribute medical devices locally in Malaysia.

Barriers

All foreign companies need to work with a Malaysian Bumiputra company that is registered with the Malaysian Ministry of Finance in order to bid for government tenders. Hence, most of the government tender information available online is in the local language, Bahasa Malaysia.

The Malaysian government is actively promoting local manufacturing of generic drugs and medical devices. There are instances of government procurement favoring locally produced and manufactured drugs, products, and equipment—even when the bidding foreign companies' pricing is far lower and the products and equipment are of equal or superior quality.

Trade Events

SE-Asian Healthcare Show

April 11–13, 2016 • Kuala Lumpur, Malaysia • abcex.com/usa

One of the region's most established trade shows, covering the entire healthcare industry.

Regional visitors include Singapore, Indonesia, and other neighboring countries.

APHM International Healthcare Conference

June 1–3, 2016 • Kuala Lumpur, Malaysia • aphmconferences.org

The Association of Private Hospitals of Malaysia (APHM) annual conference and exhibition. A significant annual medical event.

Resources

- Healthcare Procurement, moh.gov.my/english.php
- Government Health Plans, rmk11.epu.gov.my/index.php/en

Mauritius

Summary

Mauritius has a strong foundation in healthcare, medical travel, wellness, alternative medicine, medical devices, and medical education. Mauritius' healthcare infrastructure includes:

- 5 major public hospitals
- 11 private specialized clinics
- 6 specialized ic hospitals
- 29 medical laboratories
- 17 private multi-specialty clinics

Although the infectious diseases of the past have been largely eliminated, Mauritius now faces growing problems of non-communicable diseases including heart disease, diabetes, stroke, cancer, tobacco and alcohol related diseases and mental illness. It is estimated that 20 percent of Mauritian adults aged thirty and over have diabetes, 30 percent have hypertension, and 40 percent are overweight. Consequently, there is growing emphasis on living a healthy lifestyle with a focus on preventive care and doing a better job in tackling chronic illnesses.

Major government-owned hospitals and health clinics are being upgraded and the GOM issues tenders on a regular basis for medical and general equipment as well as for the procurement of pharmaceutical products, drugs and disposables.

The government is also seeking to promote medical tourism which is one of the fastest growing economic sectors in Mauritius. The number of foreign patients coming to Mauritius for treatment has increased significantly over the past few years. More and more foreign patients are choosing Mauritius for treatment in specialty areas such as ophthalmology, plastic and cosmetic surgery, cardiology and cardio-thoracic surgery.

Mauritius has also experienced sustained growth in the life sciences sector over the past few years. This sector has significant opportunities in areas of pharmaceutical manufacturing, medical devices and clinical research. Other

Statistics

Capital: Port Louis
Population: 1.3 million (2014)
GDP (USD): 12 billion (2014)
Currency: Mauritian rupee (MUR)
Language: English, French

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areas with high growth potential include medical education and medical knowledge process outsourcing

Market Entry

To enter the Mauritian market, the use of a locally established agent or distributor is strongly recommended. Local agents have the contacts and the local knowledge of customs and preferences to introduce a product or service and to develop a customer base.

For products requiring regular servicing such as high end medical equipment, qualified personnel and a reasonable supply of parts are essential for success.

Also, we recommend that U.S. companies join a local partner while bidding for large government healthcare projects, such as the construction of specialized hospitals. In evaluating bids, the authorities often give points to bidders that have a local partner they could contact, especially in projects requiring after-sale support services.

Current Market Trends

The local market for medical and pharmaceutical products is estimated at USD 110 million and is expected to grow in light of the government's plans to upgrade and expand the local healthcare infrastructure. Also as a result of a fall in fertility and an increase in life expectancy, demand for specialized healthcare services and facilities associated with an ageing population is expected to grow. Currently 12 percent of the population in Mauritius is aged 60 and above and it is estimated that this will reach 21 percent in 2027 and 30 percent by 2052.

Main Competitors

Mauritius imports its medical/pharmaceutical products from a variety of sources. With regard to medical equipment, the main suppliers are U.S., France, South Africa, Germany, India, whereas for pharmaceutical products, India is a leading supplier, followed by France, South Africa, U.K, and Switzerland. Import of medical equipment from the United States in 2014 amounted to about 15 percent of total imports.

Major U.S. healthcare brands represented in Mauritius include GE Healthcare, 3M, Abbott Laboratories, Alcon, Medtronic, Newport Medical Instruments, Pfizer, Eli Lilly, Bristol-Myers and Squibb, and Merck.

Current Demand

The government's plan to modernize and expand healthcare facilities throughout the island has generated sales opportunities for a wide range of medical devices and equipment.

Best prospects include:

- Magnetic Resonance Imaging (MRI) apparatus
- X-ray apparatus
- Radio therapy bunker
- Operating theater equipment/instruments
- Artificial parts/joints of the body
- Dental surgery and dento-facial orthopedics
- Consultancy services and equipment for specialized diabetes research and treatment centers
- Consultancy services and equipment for specialized centers for elderly care and rehabilitative medicine
- Wellness centers and health resorts
- Healthcare IT solutions to computerize health records
- Services and equipment for a National Cancer Care Center

Registration Process

There are no clear cut regulations for the registration of medical devices/equipment in Mauritius. According to the Ministry of Health and Quality of Life, each request is assessed on a case-by-case basis. At the very least, products should either be FDA approved or carry the CE mark. Request for registration should be submitted to the Ministry of Health and Quality of Life. Application for registration should be accompanied by a full product description, including brochures/samples.

Barriers

There are no specific barriers for U.S. companies entering the Mauritian market. The small size of the Mauritian market (1.3 million people) and the vast distance (10,000 miles) between Mauritius and the United States negatively influence freight costs and therefore the competitiveness of U.S. products vs. their European and Asian counterparts. U.S. companies entering the Mauritian market must contend with well-established European and Asian competitors. Also, as mentioned above, medical devices need to carry the CE mark and/or be FDA approved.

Resources

- Pharmaceutical Association of Mauritius, pharmassociationmauritius.org

A vertical graphic of the Mexican flag, showing the green, white, and red stripes and the national coat of arms (an eagle on a cactus with a snake) in the center.

Mexico

Summary

Mexico is a big market for all types of medical devices. Imports of equipment, instruments, disposable, and dental products reached USD 4.1 billion in 2014.

Imports of U.S. products are duty free if they comply with the NAFTA certificate of origin. U.S. products are appreciated because of their high quality, after sales service and good prices compared to competing products of similar quality. U.S. companies should take advantage of geographical proximity to start or increase their presence in Mexico.

Market Entry

All medical equipment and devices can be imported duty free with a NAFTA certificate of origin. Imports are subject to a 16 percent VAT tax.

All medical and health care products that touch or affect the human body must be registered with the Mexican Secretariat of Health (SSA) prior to sale or use in Mexico. Foreign manufacturers need a legally appointed Mexican distributor/ representative, who will be in charge of obtaining the sanitary registration/ market approval and will be the responsible for the product(s) in Mexico. U.S. Commercial Service Mexico can provide a detailed list of requirements and advice for processing market approval in Mexico for U.S. medical devices.

Current Market Trends


Most large public and private hospitals try to have modern and very specialized medical devices. Some medium and small private hospitals with limited budgets buy used or refurbished equipment. Public hospitals by law, cannot buy used or refurbished products. In order to save resources, recently many public and private hospitals are hiring companies that offer “integral surgery services” and provide service “per event,” offering all the necessary products required to perform a surgery. This concept is being expanded to other areas where hospitals can use

Statistics

Capital: Mexico, D.F.
Population: 120 million (est. 2013)
GDP (USD): 1.26 trillion (2014)
Currency: Mexican peso (MXN)
Language: Spanish

Contact

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integral suppliers for different processes like sterilization or others. In this way, hospitals avoid making large investments in materials, pharmaceuticals, and instruments, and also reduce the costs involved in keeping and controlling inventories, and maintaining instruments for specialized surgeries.

All public institutions ask suppliers to register with their organization. These institutions may award purchases under USD 3,100 directly to a selected provider. Purchases over that amount must be done through public tenders.

All private health care facilities select suppliers by requesting price quotations. Their decisions are based on the best equipment at the best price.

Main Competitors

Most large international corporations offering medical devices have a presence in Mexico. Medium and small foreign suppliers usually sell through legally appointed distributors.

Current Demand

Public health care institutions account for 70–80 percent of total medical services provided nationwide while private health care institutions cover approximately 25–30 percent of the Mexican population, including 32 million people with private medical and accident insurance. Some patients affiliated to social security also have private medical insurance.

In the public sector there are 1,169 hospitals of which, 194 are highly specialized medical units. In the private sector, of the 3,560 hospitals, only about 100 have over 50 beds and offer highly specialized medicine. Most of the hospitals offering specialty health care services are located in medium and large Mexican cities. There are also some medium sized private hospitals that offer specialty services and focus on high income, insured patients.

Imports supply about 80 percent of medical equipment and instruments and about 40 percent of medical disposable and dental products. In 2014, total imports in these four groups of products reached USD 4.1 billion. Of these imports 55 percent, or USD 2.3 billion dollars, were of U.S. origin. Main competitors are from Belgium, Brazil, Canada, China, France, Germany, Israel, Italy, Japan, Netherlands, South Korea, and the UK.

Barriers

Obtaining the sanitary registration/market approval is very technical and time-consuming. However, products already approved by the U.S. FDA should not have any problem in being approved in Mexico. However, due to the workloads they face, there have been some delays in receiving registration/marketing approvals from COFEPRIS in the last two years.

Also, the Mexican sanitary agency COFEPRIS has worked closely with the industry to deregulate products that do not offer risk for the patients. On December 22, 2014, COFEPRIS

published an agreement containing a list of 2,242 products that are no longer considered medical devices, and then, do not require sanitary registration/market approval in Mexico and can be freely imported. The idea is that this list will be updated periodically. COFEPRIS is also analyzing other ways to expedite the sanitary registration of FDA approved medical devices.

To be imported into Mexico, some medical products need to comply with technical standards or NOMs (Norma Oficial Mexicana). Classification is based on the Harmonized System (HS).

There are few Mexican standards for medical devices, but various agencies are preparing more standards to be issued in the near future. Updated information on NOMs and other sanitary processes is available through COFEPRIS (www.cofepris.gob.mx), the Mexican Agency in charge of registering and approving medical devices.

Trade Events

AMIC Dental

November 11–15, 2015 • Mexico City, Mexico • amicdental.com.mx

Expomed

June 2016 • Mexico City, Mexico • expomed.com.mx

Expo DICLAB

September 2016 • Mexico City, Mexico • expodiclab.com

Clinical and scientific laboratory products.

Specialized events are also organized by medical academies and associations, and may be excellent opportunities for companies offering high-technology medical devices.

Resources

Public Institutions

- www.cofepris.gob.mx
- imss.gob.mx
- cenetec.salud.gob.mx
- www.salud.gob.mx
- www.issste.gob.mx

Private Hospitals

- grupoempresarialangeles.com
- medicaltravel.com.mx
- hsj.com.mx
- medicasur.com.mx
- abchospital.com.mx

Available Market Research

- Health IT Market Overview (2012)
- Medical Devices Sanitary Registration (2011)
- Medical Devices Labeling (2010)

Morocco, Kingdom of

Summary

The Health Market in Morocco is a growing sector that is full of opportunities for future investment. The government remains the main Health care provider since 70 percent of the population goes to public hospitals. There are five University Hospital Centers and six military hospitals that are located in the large cities such as Casablanca, Rabat, Fes, and Marrakech. In addition, there are 137 hospitals in the public sector. The private sector healthcare market is growing rapidly as there are 360 private clinics, and 9,661 specialist doctors in Morocco.

The government spends around 5 percent of the gross domestic product on the healthcare sector.

The Healthcare System is comprised of AMO (Mandatory Health Insurance), which is divided into “La CNSS” (private) that reimburses up to 70 percent and “La CNOPS” (public), that reimburses up to 80 percent. Additionally, we can find RAMED which is a health care system based on the principle of social assistance and national solidarity in favor of low income individuals. There is also a separate health care system that is solely dedicated to the military.

A number of development organizations have come to support Morocco over the years in realizing its goal of achieving universal health coverage. The African Development Bank approved a EUR 115 million loan in December 2013 to help finance the third phase of Morocco’s programme to reform medical coverage (Programme D’Appui à la Réforme de la Couverture Médicale, PARCOUM III), set to be rolled out in 2014.

Market Entry

Moroccans base business on trust and mutual respect. However, U.S. exporters should be patient; procedures take more time in Morocco, as compared to the United States. Also, U.S. companies should work closely working with a locally-

Statistics

Capital: Rabat
Population: 32.9 million
GDP (USD): 104 billion
Currency: Dirham (NOK)
Language: Arabic, Berber (official);
French, Spanish

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based agent or distributor, so that they can provide U.S. companies with essential knowledge of key contacts, customs regulations, and specific opportunities. U.S. companies should also fully understand the regulatory environment and procedures before jumping into the market to avoid problems. Also, Morocco's American Chamber of Commerce (Amcham) can organize collegial and informal meetings in Casablanca with other Amcham members to gain insight into the evolving market and learn how to best position product sales for the market. In addition, the U.S. Commercial Service in Morocco provides counseling to determine the best market entry strategy for any given U.S. company/product/service such as for joint venture partners, resellers, agents and distributors.

Current Market Trends

The medical device market is estimated at USD 236 million with USD 181 million constituting imports. The market is forecast to grow at a 7 percent in the period of 2013–18. Medical device imports supply approximately 90 percent of the market. As the local medical device manufacturing industry remains at an embryonic stage, most sectors of the market rely on imports. Medical equipment prospects are increasing for public and private sector opportunities for U.S. companies. The Moroccan government is planning to build four CHU by 2018, as well as develop emergency and mobile hospital units. The Ministry of Health requires all second-hand medical equipment to be registered within 12 months of purchase. Importation of refurbished equipment is allowed for both public and private entities. A new law has been submitted banning the purchase of used medical devices and equipment. This law is expected to be implemented late 2015 or early 2016 since it has already been voted for. This is expected to improve the quality of medical equipment and offer a better quality of medical care to patients treated in Morocco. Refurbished equipment has a market with private entities.

Main Competitors

Currently Morocco does not manufacture medical equipment. The local production is limited to medical disposables. United States, Germany and France are the main suppliers. However, there is an increasing demand on Chinese and Korean equipment.

Current Demand

Public hospitals represent 85 percent of the demand and the private clinics 15 percent. By 2018, the Moroccan government is planning to achieve their goal of building four Hospital University Centers which will be a huge opportunity for U.S. companies to create partnership with Moroccan companies and export U.S. medical equipment. Also, Morocco is planning to develop emergency and mobile hospital units which could be a good opportunity for U.S. companies. Disposables and specialty medical devices are good prospects for U.S. companies. Subsector best prospects include magnetic resonance imaging and ultra-sonic scanning equipment, x-ray equipment, emergency aid equipment, monitoring and electro-diagnostic

equipment, computerized tomography equipment, and ICT (E-medicine, equipment and related software).

Registration Process

To proceed with the registration of medical equipment with the DMP (Department of medicine and pharmacy), several documents are needed:

- CE certificate or similar
- Certificate of free sales or FDA
- Declaration of conformity
- ISO13485
- Technical files and quality test details
- Original catalog

The average time to obtain a certificate of registration is six months.

Barriers

The main languages spoken in Morocco are French and Moroccan Arabic, which provides a challenge for English-speaking companies. Another potential problem for U.S. companies is that Morocco is seen as a relatively small market for medical equipment, and there are many regulations that have the ability to hinder trade. Also, some customs procedures are not uniformly applied. Bribery, corruption and requests for payoffs are another issue that U.S. investors can be confronted to (When foreign bribery prevents you from competing fairly on the basis of price, quality or service). In addition to these barriers, Morocco had tariffs placed on some medical equipment imports:

- Free of custom duties if the product is 100 percent made in the country of importation
- 10 percent of custom duties are applied if the products are manufactured in Morocco in order to protect the Moroccan industry.
- 2.5 percent tariff rate if less than 100 percent of the product is made in the country of importation

Trade Events

Medical Expo

March 2016 • Casablanca, Morocco

Aortic International Cancer Conference

November • Marrakesh, Morocco

Resources

- Healthcare Procurement, sante.gov.ma
- Government Health Plans, www.marchespublics.gov.ma/pmmp

Mozambique

Summary

Health services in Mozambique are provided at the primary level by health posts and health centers, secondary level by rural hospitals and district hospitals; tertiary level by general and provincial hospitals and at the quaternary level by central hospitals. This is equivalent to one health unit per 15,000 inhabitants with only 40 percent of the population having access to these health facilities. The rest are covered by traditional medicine, community health agents, elementary agents and traditional birth attendants. Very few have private healthcare coverage, and these are mainly found in the larger urban areas.

Communicable diseases remain the main health challenges in Mozambique. The HIV/AIDS pandemic is now responsible for a third of all deaths, and the mortality rate for children under five suffering from malaria is 1,159 per 100 000. Non Communicable Diseases are also on the increase, such as hypertension, which affects a considerable portion of the population.

Large increases in health sector investment and policies favoring upgrading and expanding the public sector health network have prioritized maternal and child health in Mozambique and, over the past decade, Mozambique has achieved substantial improvements in maternal and child health indicators. Over this same period, the government of Mozambique has continued to decentralize the management of public sector resources to the district level, including in the health sector, with the aim of bringing decision-making and resources closer to service beneficiaries. Weak district level management capacity has hindered the decentralization process, and building this capacity is an important link to ensure that resources translate to improved service delivery and further improvements in population health.

Statistics

Capital: Maputo
Population: 24.7 million (2013)
GDP (USD): 28 billion (2013)
Currency: Mozambican metical (MZN)
Language: Portuguese

Contact

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Market Entry

Personal connections and relationships are key for doing business in Mozambique. Using an agent or distributor helps to establish and secure a market presence in Mozambique. Agents help companies overcome licensing and other time-consuming requirements, as well as stay abreast of regulatory changes. In general, finding a reliable agent or distributor requires a visit to meet with local businesspeople. The U.S. Commercial Service in Maputo can assist U.S. companies interested in a relationship with local partners.

Many companies note the value of establishing a local office in Mozambique to assist in dealing with local officials and clients. At a minimum, this involves registration with three ministries, namely: The Ministry of Industry and Commerce; Ministry of Planning and Development; and Ministry of Finance. In addition, consultation with CPI is recommended to learn about tax breaks and other incentives that exist for certain types of investments. Licensing and other time-consuming requirements remain a problem, and institutionalized red tape can obstruct or delay the securing of local licenses and permits. Coordination with the relevant government ministries or regulatory agencies is important to avoid unnecessary delays. Most U.S. companies hire a consulting company to assist with the registration process, and small-to-medium-sized companies can expect to experience longer delays.

Current Market Trends

Mozambique is a low income country and its infrastructure is underdeveloped, due to the protracted civil war that lasted from 1977–92. However, the Mozambican government continues to show its commitment towards the development of healthcare infrastructure by tackling the country's shortages of health professionals and clinic with the aid of foreign investors. Estimated value of medical device sales for 2014 was USD 35.6 million, and is projected to rise to over USD 50 million in 2015 and USD 78 million by 2016. Diagnostics and consumables have the highest values. (Source: BMI)

The building of a USD 6 million drug production facility which is state-owned. Sociedade Moçambicana de medicamentos will help the country reduce its dependence on drug imports as it increases production capacity and begins to package Brazilian manufactured drugs (Source: BMI).

The government is also planning to offer cervical cancer vaccination to young women. A pilot project was rolled out in 2014, with a wider roll out by 2016, offering opportunities for manufacturers in the country.

Registration Process

You must obtain market authorization from the Health Ministry of Mozambique to commercialize your medicine in Mozambique. The primary components of registration include:

- Summary of process administrative information
- Chemical and pharmaceutical documentation
- Characteristics of medicine
- Documentation on security
- Documentation on effectiveness

Barriers

Lack of distribution networks and infrastructure is problematic, often leading to drug scarcity. Theft of medicines and equipment is also an issue, as well as an abundance of counterfeit drugs. There is a wide gap between the quality of healthcare provision in rural and urban areas. Over-reliance on traditional medicine may slow market growth.

Resources

- Mozambique Ministry of Health, www.misau.gov.mz

The Netherlands

Summary

Although the policy and regulatory environment is fairly transparent, it can be challenging for U.S. companies to navigate through the complex healthcare landscape, stay apprised of changes, and find out how to take advantage of opportunities. There are many opportunities, however, for innovative U.S. technology.

Market Entry

The regulatory environment for data security is very strict while language barriers are an additional challenge in this highly-technical sector. U.S. companies must be familiar with Dutch regulations and EU directives on product registration, marketing, and health/safety standards. It is therefore advisable to work with a local partner/distributor.

Since July 1, 2013, the European Directive 2004/18/EC on public procurement applies to all hospitals for the purchase of medicines and medical devices. The directive requires that for purchases over the threshold of EUR 200,000 a European tender should be released and published in the supplement of the Official Journal of the European Union. Procurement with a threshold between EUR 85,000 and EUR 200,000 requires a tender in the Netherlands and publication in the Official Journal.

Current Market Trends

The healthcare system in the Netherlands is facing multiple challenges. The aging population and higher health expectations will have an important impact on healthcare policy and public expenditures in the coming years. Cost-saving measures are well-received and the Dutch are looking for technical advancement and medical innovations. Orthopedic products, homecare products, obesity and diabetes products have good market potential. Furthermore, there is a trend

Statistics

Capital: Amsterdam
Population: 17.1 million
GDP (USD): 800 billion (2014)
Currency: Euro (EUR/€)
Language: Dutch

Contact

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towards miniaturization of medical devices, which allows minimally-invasive and non-invasive procedures.

Medical software, telemedicine and e-health are also sectors with a strong market potential. Health IT is in an embryonic stage at the moment with great opportunities in the bio-informatics and life-sciences sectors. The Dutch realize significant savings can be made by investing in health IT. In the absence of continued investments, healthcare spending is estimated at 18 percent of GDP in 2020. With the smart use of IT-tools, costs can be reduced to 5.3 percent of GDP. Annual savings of USD 3.2 billion are expected as a result of the effective use of IT-tools while unnecessary hospitalization and deaths will be reduced by 50 percent. Educating people on the use of IT-tools is a priority.

Last, but not least, there is a trend towards treating chronic diseases with new technologies allowing patients to stay home and minimizing the impact on their quality of life.

Main Competitors

A number of medical device companies have their European Headquarters in the Netherlands, including Medtronic, Stryker Europe, and NuVasive.

They face strong competition from Dutch and foreign companies like F.Hoffmann-La Roche, DePuy, Essilor International, Philips Medical, Siemens Healthcare, GE Medis Leyden, TNO, and KPN.

Current Demand

All innovative technologies can expect to do well in the Netherlands, including minimally invasive and non-invasive equipment, user friendly homecare products, e-Health, orthopedic and implantable products, and diabetes products.

Registration Process

Medical Devices:

The Healthcare Inspectorate oversees the quality and usage of medical devices. A “medical device” is any product other than a pharmaceutical that is used for medical purposes. Examples range from a simple sticking plaster to a pacemaker or surgical instruments.

The classification also covers the software that some products require in order to work properly. One notable group of medical devices is that of the in-vitro diagnostic tests, such as those used to determine pregnancy or HIV infection.

The Inspectorate ensures that the manufacturers and suppliers of medical devices observe all relevant legislation, and takes action in the event of a breach of the regulations. The Inspectorate evaluates all incoming reports about malfunctions or quality issues relating to

medical devices. It also oversees the activities of DEKRA Certification, the “notified body” for the Netherlands.

All countries have a notified body, being the independent, government-approved testing and certification organization which verifies whether medical devices meet all quality requirements and the specifications laid down by law. A manufacturer may choose which of the European notified bodies is to inspect and assess its products. The Inspectorate also ensures that manufacturers fulfil the legal requirement of notifying certain groups of medical devices to the CIBG, an agency of the Ministry of Health which maintains the various registers.

Medical devices are also governed by a number of EU Directives:

- Directive on Standards for Active Implantable Medical Devices (90/385/EEC)
- Directive on Medical Devices (93/42/EEC)
- Directive on in-vitro diagnostic medical devices for (98/79/EC)

Various sets of guidelines (“MEDDEVs”) have been compiled to facilitate the implementation and interpretation of the legislation and can be found at bit.ly/1fsHwEb.

Medicines

Manufacturers, distributors and importers of medicines intended for human use must hold a Manufacturing or Wholesale Authorization. The Inspectorate enforces this legal obligation in the Netherlands.

All other European member states have a similar agency charged with this task and the Inspectorate cooperates closely with them. Supervision applies to both registered drugs and those currently undergoing clinical trials.

The inspections are primarily concerned with compliance of the Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) guidelines. Manufacturers based in countries outside the European Union are also subject to inspection on the authority of the European Medicines Agency (EMA, ema.europa.eu) and the Dutch Medicines Evaluation Board (CBG, english.cb-g-meb.nl).

In addition to the overall status, these inspections assess individual products for compliance with the terms and conditions of their (European) marketing authorization. The Inspectorate also conducts GMP inspections of the manufacturers of veterinary medicines, doing so in association with the relevant department of the Medicines Evaluation Board. Licensing for manufacturers is governed by the terms of the Veterinary Medicines Act.

Applications for Manufacturing or Wholesale Authorizations should be submitted to Farmatec (farmatec.nl). If the Inspectorate finds that a manufacturer is indeed complying with the GMP guidelines, it will issue a GMP certificate. The Inspectorate also advises the Minister of Health on issuing or revising Manufacturing or Wholesale Authorizations.

On request, the Inspectorate will also advise the Medicines Evaluation Board about licensed manufacturers (for the purposes of “site clearance”). The manufacturers of the active pharmaceutical ingredients do not need a Manufacturing Authorization. Nevertheless, GMP inspections of these companies will be conducted at the request of the EMEA, CBG, the European Directorate for the Quality of Medicines or the manufacturers themselves.

Barriers

There are no trade barriers against U.S. products and services.

Trade Events

eHealth Amsterdam

June 8–10, 2016 • Amsterdam, Netherlands • ehealthweek.org

Resources

- European Tender database, ted.europa.eu
- EU eHealth Action Plan, bit.ly/1IsiRNb
- NIVEL Institute (Dutch research institute for the healthcare sector), nivel.nl/en

New Zealand

Summary

All New Zealanders have access to a sophisticated, high-quality healthcare system. New Zealand's health system is comprised of public, private, and voluntary sectors that coordinate to provide and fund healthcare. Around 85 percent of healthcare is government-funded. Due to an aging population, New Zealand's total health expenditure by 2050 is due to rise to 12.5 percent of GDP. The government's health budget for 2015–16 is approximately USD 11 billion. (Source: New Zealand Treasury). Both the public and private sectors aim to source the best and most-affordable technologies.

The U.S. is an important and significant healthcare supplier to New Zealand providing approximately 40 percent of total market demand. U.S. companies specializing in healthcare products have a strong reputation in New Zealand based on performance, cost, and reliability. Opportunities exist for U.S. companies specializing in new innovative technologies that reduce overall patient costs leading to faster patient recovery and reduced rehabilitation costs.

Market Entry

U.S. companies should establish a local sales presence to improve their market position and chances of success in New Zealand. While some companies will open a subsidiary in New Zealand, for most U.S. exporters this means appointing an agent or distributor. We encourage U.S. companies to research three key determinants: the purchasing practices of their target customers, the competitive climate in the New Zealand market, and the importance of after-sales service.

New Zealand government tenders are advertised on the Government Electronic Tenders System (GETS, gets.govt.nz). Subscription to GETS is free.

Statistics

Capital: Wellington
Population: 4.6 million
GDP (USD): 158.9 billion (2014)
Currency: New Zealand Dollar (NZD)
Language: English (official), others

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Current Market Trends

Health targets are currently the basis of New Zealand's key health strategies. This country's health targets focus on chronic diseases (diabetes, heart disease, cancers and obesity), child and youth services, primary healthcare, elderly care, elective services and infrastructure. Health targets are linked with extra government funding. For example, government investment in building new elective surgery theaters is beginning to help reduce the rising patient numbers for non-emergency surgical treatments.

New Zealand's aging population increases the demand for facilities such as retirement villages with on-site hospitals.

Main Competitors

U.S. companies can expect to face competition in this market from major global suppliers including other U.S. healthcare suppliers. New Zealanders recognize U.S. brands as reliable, robust but not always price competitive. Australia is New Zealand's nearest neighbor and across all sectors its most important trading partner.

Current Demand

The country's aging population influences public healthcare expenditure plans whilst at the same time the government is committed to delivering essential healthcare services. Higher living standards are contributing to an increase demand for medical equipment. New Zealanders expect accessibility to advanced equipment to manage chronic diseases (chronic diseases account for around 80 percent of healthcare use). Value for money is a key procurement-making decision. New, innovative technologies are important to meet this objective.

A third of New Zealand's population is concentrated in the Greater Auckland region. Approximately 80 percent of the population is urbanized. Specialist services are readily available in the main centers of Auckland, Wellington and Christchurch. Auckland is the leading center for advanced medical care in New Zealand.

Registration Process

New Zealand Medsafe (medsafe.govt.nz)—the New Zealand Medicines and Medical Devices Safety Authority, part of the Ministry of Health—regulates by applying a framework that weighs up risks and benefits of medicines and medical devices, ensures there are therapeutic benefits, and manages the potential risks associated with use of these products. MedSafe manages a Web Assisted Notification of Devices (WAND). If not exempted, companies must notify their medical devices to MedSafe via the WAND system. For imported products, the New Zealand resident sponsor undertakes this process. There is no fee for notifying WAND or maintaining a notification.

Nigeria

Summary

The Nigerian healthcare sector is presently grossly underdeveloped and does not meet local needs. Much of the healthcare infrastructure is confined to major cities with people living in urban areas getting four times as much access to healthcare as those living in the rural areas. The private health sector is highly fragmented, consisting of many small medical facilities that are privately owned by medical professionals. Most of these hospitals have fewer than 10 beds and few facilities.

According to a 2015 BMI report, there were an estimated 3,534 hospitals in 2014, of which 950 were in the public sector. These include 54 federal tertiary hospitals comprising 20 teaching hospitals, 22 federal medical centers, three national orthopedic hospitals, the National Eye Centre, the National ENT Centre and 7 psychiatric hospitals, which are overseen by the Hospital Services Department of the Federal Ministry of Health (FMOH). The private sector is the dominant provider of care in many areas, accounting for the greater part of secondary care facilities. In 2005, the FMOH estimated that there were around 9,000 private health facilities, but information on their location and the level of care provided was patchy. Private health facilities are thought to include around 2,600 private hospitals and clinics. Nigeria had an estimated 134,000 hospital beds in 2014, equal to 0.8 per thousand populations, well below the rate for the African region. The number of hospital beds is estimated to have grown at a compound annual growth rate (CAGR) of 3.8 percent since 2009, slightly higher than population growth, but at an insufficiently high rate to have a significant impact on the population bed ratio. The number of doctors is estimated to have grown at a CAGR of 2.7 percent since 2009, reaching 66,555 in 2014. Numbers have grown in line with population growth meaning that the rate per thousand populations has remained at 0.4, which compares to 0.8 doctors per thousand populations in South Africa. Provision of nurses is also limited with 1.5 nurses per thousand populations equal to around 268,000. The number of dentists is extremely low with less than 3,000 registered in 2014.

Statistics

Capital: Abuja
Population: 170,123,740 (est. 2012)
GDP (USD): 509 billion (2014)
Currency: Naira (NGN)
Language: English (official),
Igbo, Yoruba, Hausa

Contact

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Despite these recent improvements, Nigeria's health infrastructure still remains low and insufficient to cater for its growing population. As a result, each year, over 30,000 Nigerians travel to India, the United Arab Emirates, the United States, South Africa and Europe on medical tourism for major treatments such as open heart surgeries, renal transplants, brain surgeries, cancer and eye treatment. An estimated USD 1 billion is spent on these therapies. Nigeria's health sector contribution to GDP is 5 percent and the country remains a net importer of medical equipment and prescription medicines. Local production of medical devices is limited to peripheral items such as hospital beds and gurneys. Local pharmaceutical manufacturing companies have the capacity to produce only over-the-counter drugs especially those for treating common cold, malaria and headaches as well as some low end prescription remedies. Prospects exist for U.S. companies largely in the medical diagnostics domain. Magnetic Resonance Imaging (MRI), Computed Tomography scan (CT), Digital X-Ray, Ultrasound, Mammography, ultrasound scans, as well as anesthesia technologies will do well.

Though in 2013, the government announced a zero tariff on imported medical equipment, pharmaceutical manufacturing machinery and packaging materials, industry sources say the legislation has not yet been implemented. A duty rate of 20–25 percent on medical equipment still applies. Imported drugs attract a 10 percent rate while 5 percent is charged on pharmaceutical manufacturing equipment and packaging materials. Nigeria's healthcare professional associations include: the Nigerian Medical Association (NMA, nigeriannma.org), Association of General and Private Medical Practitioners of Nigeria (AGPMPN, agpmpn.org), Association of Medical Laboratory Scientists of Nigeria (AMLSN, amlsn.org), Pharmaceutical Society of Nigeria (PSN, psnnational.org), and Healthcare Federation of Nigeria (HFN).

According to the International Finance Corporation (IFC), the private sector will be the primary driver of growth as healthcare demand in Africa is projected to grow to USD 35 billion by 2016.

Market Entry

The best way for U.S. manufacturers and suppliers to penetrate the Nigerian market is by taking advantage of the matchmaking services and programs of the U.S. Commercial Service. We encourage U.S. companies to first seek the assistance of a U.S. Export Assistance Center (USEAC) before exploring opportunities in the Nigerian market. For establishing a presence in Nigeria, we recommend that U.S. companies use agent/distributor relationships with local companies vetted by the U.S. Commercial Service in Nigeria. Contractual terms and conditions must be fully spelt out with local partners and we recommend using the services of an attorney.

Current Market Trends

Consumer health has been gradually growing in the past 5 years due to increasing health awareness. However, many Nigerians still resort to self-medication rather than visit a hospital when in need of medical care. This is largely due to the perceived high cost of hospital

treatment. About 61 percent of Nigerians lived on less than USD 1 a day according to country's statistics bureau, while 69 percent of health payments are out-of-pocket according to the health ministry. The rich and wealthy seek specialized care outside overseas because of the dearth of professional medical personnel and dilapidated health infrastructure. Over the years, poor remuneration has forced many healthcare professionals to seek opportunities abroad especially in Europe and the United States. The President of the Association of Nigerian Physicians in the Americas says the number of Nigerian doctors in the U.S. alone is between 4,000 and 5,000. Labor strikes by doctors employed both by federal and state hospitals are a regular feature. Thus, patients are often driven to seek medical attention from private clinics.

Despite these challenges, the Nigerian healthcare sector is expected to grow under the government's National Strategic Health Development Plan (NSHDP) introduced in 2010. Under the NSHDP, the federal government of Nigeria and its institutional partners plan to spend USD 26.7 billion in the construction and upgrade of hospitals, diagnostic centers and laboratories, procurement of modern medical equipment and drugs as well as manpower development. The Nigerian Health Insurance Scheme (NHIS) established in 2004 by the Nigerian government as its flagship affordable health insurance institution with the oversight to provide universal health coverage to its citizens, has licensed 60 Health Maintenance Organizations (HMOs). Though most of those enrolled into the NHIS program are public sector employees, private sector organizations and individuals are fast joining. According to the NHIS, about 7.2 million Nigerians have so far been registered. It targets to have 100 percent of the population insured by 2020. This trend is expected to significantly increase the number of people with access to hospital care and reduce out-of-pocket payments.

A report published by Euromonitor International in May 2014 indicates that independent drug stores remain the major channels of distribution of consumer health products including medicines. Direct selling continues to be a relatively important sales method, which is partly responsible for driving overall growth of consumer health. Internet retailing, however, remains insignificant, although enjoying growth.

Main Competitors

According to industry contacts, European products dominate the Nigerian market but China and India, have made significant inroads especially in the pharmaceutical and low end medical devices segment. Asian manufacturers largely employ direct marketing methods and often travel to Nigeria to visit with suppliers and hospitals as part of their business development tactics.

Current Demand

Demand for diagnostic related equipment and technologies such as Magnetic Resonance Imaging (MRI), Computed Tomography scan (CT), Digital X-Ray, Ultrasound, Mammography, ultrasound scans, as well as anesthesia kits and mortuary equipment have increased

significantly since the introduction of the National Strategic Health Development Plan (NSHDP). The country's healthcare priorities which include, polio eradication, maternal and infant care, malaria and tuberculosis control, pandemic influenza prevention and control, non-communicable disease prevention, and Ebola outbreak prevention amongst others, have driven investments in vaccines, drugs and medical facilities by the government, Non-Governmental Organizations (NGOs), multilateral agencies and the private sector. Malaria and tuberculosis constitutes Nigeria's most prevalent disease burden. World Health Organization (WHO) statistics indicate that nine out of 10 deaths which occur in Sub-Saharan Africa (including Nigeria) especially amongst young children and pregnant women are related to malaria. With respect to TB, Nigeria ranks 10th of the 22 high-burden TB countries in the world. Used medical equipment is in high demand especially by small and mid-sized private health clinics, diagnostic centers and laboratories due to their small budgets. Price and after sales support are the most competitive factors when selling to Nigeria.

Most Nigerian pharmaceutical manufacturing companies produce analgesics, cough mixtures and low end prescription drugs and source a reasonable portion of their active ingredients from the United States. With respect to imported medicines, Indian and Chinese products retain controlling market shares while the U.S. with its slice of about 7 percent, holds the niche market for high end antibiotics, vitamins and some natural products.

Registration Process

The National Agency for Food and Drug Administration and Control (NAFDAC, nafdac.gov.ng) regulates food and drug products in Nigeria.

- For NAFDAC's guidelines on medical devices, visit bit.ly/1D6zg7M.
- For guidelines on pharmaceutical products, visit bit.ly/1JLLTCb.

Due to the complications involved in the NAFDAC registration process, U.S. exporters are advised to encourage their Nigerian partners/associates/distributors to directly handle it by themselves. A U.S. company does not need to re-register its already registered product with NAFDAC if it decides to change its local agent or distributor. In this case, the U.S. exporter simply needs to withdraw its power of attorney from its old local representative and give it to its new partner and inform NAFDAC of the change in writing.

The Standard Organization of Nigeria (SON, son.gov.ng) is responsible for compliance with equipment specification and import standards. Importers of drug products and medical devices must first register them with NAFDAC prior to import.

Barriers

There are no barriers to trade and investments in the healthcare sector. In 2013, the government announced a zero tariff on medical devices and pharmaceutical manufacturing/packaging machinery. However, to date, the new tariff regime has not taken effect. A duty rate

of 20–25 percent on medical equipment still applies. Imported drugs 5–10 percent rates while 5 percent is charged on pharmaceutical manufacturing equipment and packaging materials.

Trade Events

Nigeria Pharma Manufacturers Expo

September 7–9, 2015 • Lagos, Nigeria • nigeriapharmaexpo.com

Medic West Africa Exhibition and Congress

October 14–16, 2014 • Lagos, Nigeria • medicwestafrica.com

Norway

Summary

Norway is one of the wealthiest countries in the world and this is reflected in its expenditure on medical care for its citizens. With the exception of the U.S. and Switzerland, Norway spends more of its GDP (8 percent/USD 35 billion) on healthcare than any other country in the world. The state-dominated medical system, covering 84 percent of total healthcare costs, is striving for technological advances and organizational improvements in a climate of budget constraints, a rise in chronic disease and an aging population. By 2025, there will be 40 percent more senior citizens in Norway than today.

U.S. companies are estimated to supply around 25–30 percent of Norwegian purchases of medical equipment. High end, quality products and a tailored marketing approach are key factors for U.S. companies in penetrating the Norwegian market. The perceived reliability and quality of a product, together with information received from health care providers/relevant certifying bodies/professional associations in Norway constitute the most significant factors in a purchasing decision for Norwegian buyers and end-users of medical equipment.

U.S. medical equipment suppliers have attractive opportunities in Norway.

Market Entry

Finding a local representative with established contacts with the public authorities is the key to success for a new-to-market U.S. company. The availability of technical service also plays an important role. Most communication is Norwegian so it is an advantage to have a local representative knowledgeable about of the current market conditions.

Statistics

Capital: Oslo
Population: 5.2 million
GDP (USD): 488 billion
Currency: Norwegian kroner (NOK)
Language: Norwegian

Contact

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Current Market Trends

There is a major health reform underway, the Integrated Health Care Reform, that is attempting to address some of the challenges the Norwegian healthcare services face. Issues include the inadequate coordination of services covering patient needs, too few initiatives aimed at limiting and preventing disease, changing demographics with an increase in chronic and complex illnesses. The aging population and increase in chronic diseases represents an extra burden for the healthcare system and the government has signaled that nursing and care for the aged must be given higher priority, as well as an increasing use of outpatient-based care at hospitals in an effort to rationalize. In addition technological advances and organizational improvements are prioritized to get healthcare costs under control and meet future challenges, so there is an high focus on healthIT solutions such as EPJ, tele and cloud based medicine and systems for integrating local/regional/national health information networks.

Main Competitors

Norway relies heavily on imported medical equipment. The major third-country suppliers of medical equipment are Germany, Denmark, Switzerland, Sweden, the United Kingdom, and Japan. The Nordic countries have traditionally had close contact and cooperation in several healthcare related areas over the last decades. Norwegian companies have also had a preference for participating in and seeking trading partners through European, and in particular German, trade events.

Current Demand

With a rapidly aging population, an increase in chronic disease and increasing healthcare costs, the Norwegian government has stated that telemedicine, e-health and welfare technology are a national priority as they are very important tools in the successful implementation of the key Integrated Health Care Reform of 2012. The authorities are implementing electronic patient journals/EPJ's, and have successfully launched e-prescriptions a national health portal where citizens will be able to have access to their digital health information. Telemedicine is seen as an important part of future acute medical care, radiology (work-sharing among hospitals) with specialist consultations within the ear-nose-throat field (video conferencing) and specialist consultations in dermatology (e.g. video conferencing and still picture technology); and cardiology (e.g. heart rhythm/sound comparisons). Also, clinical information systems, home care and personalized health systems/ services for remote patient monitoring, systems for integrating local/regional/national health information networks represent significant potential for U.S. companies. However, there are barriers to entry such as requirement for local language, privacy and data protection concerns, standardization and interoperability issues, and reimbursement issues.

Promising subsectors for U.S. suppliers of medical equipment include; surgical instruments and equipment, diagnostic apparatus, ultrasound, orthopedic equipment, monitoring instruments and equipment, laboratory/pathology instruments and equipment, digital x-ray systems, and customized ICT equipment.

Registration Process

Equipment to be sold in Norway must be registered with the Department of Health and Care Services (bit.ly/1HVNZkF) and must have EU approval (CE Mark, export.gov/eu). Norway participates in the EU internal market through the EEA Agreement (European Economic Area), and has the same rights and obligations as EU member states in regulation of medical devices. Norway applies EU product requirements, methods of conformity assessment, and duty rates for U.S. imports.

Barriers

Through the EEA Agreement (European Economic Area), Norway participates fully in the EU internal market and its efforts to establish common product requirements and methods of conformity assessment. Norway has the same rights and obligations as EU member states in regulation of medical devices. All medical devices must have pre-marketing approval and bear the CE mark confirming conformity with the essential requirements of EU/EEA directives, Medical Device Directive (93/42/EEC), Active Implantable Medical Devices (90/385/EEC) to be sold in the EU internal market.

There are no other significant barriers to trade.

Trade Events

Most Norwegian distributors attend established international trade shows such as Medica.

Resources

- Healthcare Procurement, doffin.no/en
- Government Health Plans, regjeringen.no/en/dep/hod/id421



Oman

Summary

Over the last 35 years, Oman has invested heavily in the health sector and succeeded in creating a relatively modern health care system. Health indicators attest to its comprehensive and well-developed standards: average life expectancy at birth is a remarkable 76.8 years, placing Oman on a par with many advanced Western nations. The United Nations 2010 Human Development Report listed Oman at the top of the world's 10 countries that have made the greatest public health progress in recent decades.

Market Entry

With the U.S.-Oman Free Trade Agreement entering into force in January 2009, bilateral trade in industrial and consumer products, with the exception of certain textile and apparel products, is now mostly duty free. Oman provided duty free access on virtually all products in its tariff schedule and will phase out tariffs on the remaining handful of products within a few years. More information on the FTA can be accessed at oman.usembassy.gov/us-oman-fta.html. Under the "national treatment" provisions of the U.S.-Oman Free Trade Agreement U.S. companies may register as an Omani company, with 100 percent U.S. ownership. Companies wishing to register with the Ministry of Commerce and Industry are encouraged to use the new Invest Easy online company registration system.

U.S. companies can still distribute their products in Oman using a local agent if they prefer not to register in Oman. Agents are particularly useful for sales to the Omani government due to their local contacts, language ability, and cultural knowledge. Constrained budgets encourage government procurement officials to buy direct; however, in practical terms, it is still difficult for foreign companies to sell to the government without an Omani agent scouting for and bidding on tender opportunities. As in other Gulf countries, regular, personal contact is the key to success in trade relationships.

Statistics

Capital: Muscat
Population: 4.1 million
GDP (USD): 82 billion
Currency: Omani Rial (OMR)
Language: Arabic

Contact

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The manufacturer or supplier may not unilaterally terminate the agency agreement except where there is an unjustifiable breach of agreement by the agent. Article 10 of the Commercial Agencies Law governing agency agreements previously awarded 2–3 years of profit as compensation for “unjustified” failure to renew even fixed-term agencies; however, Sultani Decree 34/2014, effective from 21 July 2014, repealed the article in question, conceivably allowing the parties to an agreement to decide the terms of renewal and termination. Regardless, the courts still have authority in disputes between principals and agents, so consultation with a lawyer in drafting an agreement is highly recommended. Agents are encouraged to register agreements at the Oman Chamber of Commerce and Industry (OCCI). Agents must register in writing and in Arabic with the Registrar of Agents and Commercial Agencies at the Ministry of Commerce and Industry (MOCI), renewable every three years. Agencies may be non-exclusive and more than one agent may be engaged to promote the same product or services. Previously, an agent was entitled to commission even if the principal has resorted to direct selling in contravention of the Commercial Agencies Law, but this article was also repealed.

Current Market Trends

The government’s determination to provide all its citizens with free basic health care, along with treating persistent diabetes and cardiovascular disease, means that health-related expenditures are growing. The country’s healthcare infrastructure now boasts around 67 modern hospitals with around 6,000 beds, a ratio of 1.5 beds for every 1,000 citizens, in addition to more than 1,100 health centers and more than 1,000 private clinics throughout the Sultanate. The Ministry of Health (MOH) is the main healthcare provider, now operating 244 health centers of which 53 have maternity beds and 24 are extended health centers. Other providers include Armed Forces Medical Services, Royal Oman Police Medical Services, Sultan Qaboos University Hospital, Diwan Medical Services, Petroleum Development Oman Medical Services, and the private sector. In 2012, the two leading private hospitals, Starcare and Muscat Private, both received Joint Commission International certification.

After the MOH brought together stakeholders, investors, and international experts at a Vision 2050 Planning Conference in early May 2012, the Omani cabinet approved OMR 1 billion (USD 2.6 billion) to upgrade Oman’s healthcare infrastructure over the next three years. A new medical city, to be located in Barka north of Muscat, is under development with a budget of OMR 570 million (USD 1.5 billion); a second complex, expected to open in Salalah in 2016, has been stalled since June 2014 over financing and other issues. The MOH will require support from specialized companies and international expertise as its Planning Division has only 11 employees and lacks the capacity to design and manage large-scale projects.

Projects that should be implemented during the new five-year plan include a new referral hospital in Muscat, at the cost of USD 358 million; a hospital in Salalah, at the cost of USD 122 million; and new hospitals worth USD 142 million in Suwaiq, Mahout, Sinaw, Dhalkut, and Al Muziunah. The MOH is planning to build eight new hospitals and renovate several existing



hospitals as part of its 36 projects planned for the Eighth Five-Year Health Plan 2011–15. Since the current Health Plan was published, the MOH has opened nine new health centers, while in September 2014 the MOH signed the contracts for 17 more centers. Highlights include: Muscat General Hospital near Muscat International Airport, three major hospitals in Ruwi, a 75-bed multi-specialty hospital in Duqm, the 4,800-square meter National Centre for Hereditary Health, a drug rehabilitation center in Sur, 17 new health centers across Oman, new kidney treatment units in Al Batinah South, a tumor ward and liver transplant center near the Royal Hospital. The MOH also has planned rehabilitation of Sultan Qaboos Hospital in Salalah (for outpatients) and Khoula Hospital (for road accident and trauma care), power transmission stations for the Royal Hospital, Al Maziouna Hospital, Dalkout Hospital, health centers at Sarfit and Al Hashman, and upgrading Khasab hospital to a referral hospital for the Governorate of Musandam. Finally, the Royal Oman Police will construct a new 400–600 bed hospital over the next three years, requiring equipment, management services, and drug imports.

The MOH has outlined other requirements including a full-fledged EMS/ambulance system, innovative health insurance solutions for the 1.8 million expat population (and eventually for citizens, currently covered by the government), customized patient catering plans, and help with recruitment to address Oman's severe shortage of doctors. Oman's Minister of Health, Dr. Ahmed bin Mohammed bin Obaid al-Saidi, announced early 2014 that the Sultanate will face a shortage of around 8,900 doctors and nurses by 2015, with 3,288 positions currently vacant. The MOH needs to send at least 50 high school graduates to an English-speaking country every year to study medicine in order to keep up with patient growth. Ministry officials are anxious to partner with U.S. universities to train and certify Omani healthcare practitioners. The MOH has also expressed specific interest in U.S. healthcare information management technologies as part of its efforts to standardize operations and establish interconnectivity among Oman's hospitals and clinics.

In addition, a private Saudi investor (Apex Medical Group) has partnered with Methodist International, a U.S. healthcare management company, to establish a USD 1 billion International Medical City (IMC) in Salalah. (Oman was chosen for its ample available land, Salalah's pleasant coastal weather, and the Sultanate's societal tolerance for international visitors staying for extended periods.) The company's goal for the IMC is to offer a world-class local option for the Gulf Cooperation Council (GCC) population currently seeking quality healthcare overseas, and to serve as a regional center of excellence for genetic diagnostics, organ transplants, and rehabilitation. The master plan for the seaside, resort-style hospital includes a 530-bed facility and educational facilities, as well as long-term villas and apartments for family members of patients from around the world. As of summer 2014, however, the project is rumored to have stalled over permitting, financing, and transplant administration issues.

Main Competitors

The Omani market offers solid prospects for U.S. health care products. The Ministry of Health is the main provider of healthcare, but there is ample room for public-private partnerships as the Ministry seeks to transition to regulator status over the long term. Oman is focused on upgrading its facilities and diagnostic capabilities. The current five-year plan includes spending slated for preliminary and secondary healthcare in addition to women's health issues, infectious and non-infectious diseases, radiology, ophthalmology, mental health, and occupational health. The Ministry of Health has expressed interest in U.S. healthcare information management technologies as part of its efforts to standardize operations and establish interconnectivity among Oman's hospitals and regional clinics.

Current Demand

The healthcare market in Oman is expected to be worth USD 3.2 billion by 2016, according to a 2014 report by corporate advisory company Alpen Capital. The report states that the market in the Sultanate is "in the developing stage," and adds that the market is expected to grow at a compound annual growth rate of 11.8 percent between 2013 and 2018 to USD 3.8 billion. In addition, the number of hospital beds required to meet this demand is anticipated to rise from an estimated 7,645 to 9,359 in the same period, with a sizeable proportion expected to be absorbed by the USD 1.5 billion Sultan Qaboos Medical City in Barka and the USD 1 billion International Medical City in Salalah (if the construction commences). At USD 150, Oman had the lowest sales per capita of medicines in the GCC in 2012, according to Alpen Capital, but has traditionally offered some of the highest pharmaceutical prices in the GCC. The size of the Omani pharmaceutical market was valued at USD 476 million in 2012 as compared to USD 431 million in 2011. (QNB Capital reported USD 152 million in spending on drugs in Oman in 2012.) Currently, Oman imports 93 percent of its medical supplies, including pharmaceutical, surgical and laboratory materials, though the government of Oman is looking to reduce its dependence on medical imports. As of June 2015, the government of Oman is implementing the second phase of a planned reduction in prices for 1,180 drugs, in accordance with a January 2013 agreement by GCC health ministers to lower drug prices. The price cuts have been welcomed by local drug manufacturers struggling to compete with imported brands, while squeezing the profit margins of established pharmacy chains. A few international players have already left the market as they were averse to reducing their product prices. Most principals have now agreed to supply at these new prices, but local chains believe it will take several years for the market to stabilize.

The 2014 budget allocated USD 3.38 billion (OMR 1.29 billion) to healthcare, an increase over the 2013 budget, which was USD 1.3 billion. Oman increased its state budget for health by 24 percent in 2015, growing to USD 4.2 billion (OMR 1.6 billion), for the construction of 11 new hospitals and health centers. The health budget accounts for 11.3 percent of the total state budget, which stands at USD 36.6 billion (OMR 14.1 billion).



Registration Process

The Ministry of Health commenced its local registration process for pharmaceutical products in 1988, following the other GCC countries. Normally, medicines, equipment, and drugs require approval of the Gulf Central Committee for Drug Registration (GCC-DR) and the MOH Oman before being released. The process is considered tedious for a market of four million people, and has discouraged many players from entry. Process duplication may occur at times where companies must re-submit registration paperwork, even if the product is registered elsewhere in the GCC.

Barriers

A number of constraints affect trade and investment in Oman. The country has a relatively small population and there is no high-value consumer market beyond the capital area. This situation is exacerbated by intense competition from nearby global trading hub Dubai and industries in Saudi Arabia. In addition, other countries in the GCC typically offer higher industrial subsidies and lower quotas for hiring nationals.

While Oman is an attractive market for a number of products and services, at times it can present challenges for U.S. companies to do business. Bureaucratic obstacles exist, including clearances for visas and permits for foreign workers, lengthy company registration requirements for consultancies, and a prohibition on real property rights for foreigners outside of Integrated Tourism Complexes. (Land ownership is not covered by the FTA.) The divide between the government and the private sector is not well-defined in Oman, leading to potential conflicts of interest. Of note are the oligarchic, closely-held companies with familial ties to government officials. Government decision-making is often opaque. Companies that have been successful in Oman usually have previous experience in the Middle East or a full-time in-country representative or office.

Of particular concern for many international companies in Oman is the “Omanization” process, wherein the government sets quotas for Omani employment on a sectoral basis. Although the FTA provides for limited exceptions for specialized upper management, U.S. companies are responsible for complying with most Omanization requirements. Many companies, both Omani and international, have noted that some of the quotas are difficult to satisfy because of the paucity of properly educated and trained Omanis. Further, obtaining labor clearances for new foreign workers can be a challenge. Despite considerable government efforts to replace expatriate workers with Omanis, Oman still heavily depends on South Asian and other foreign labor. The total number of expatriates in Oman with valid labor cards as of May 2015 was over 1.5 million, approximately 40 percent of the population. Around 80 percent of expatriate workers have only secondary education or lower, and the majority work in low-skill construction and manufacturing jobs. Around 70 percent of doctors in Oman are expatriates, a figure the government of Oman aims to reduce by 2050. The Omanization drive intensified in 2011 as “Arab Spring” demonstrators demanded more opportunities for Omanis. The

government estimates up to 50,000 new jobs per year are needed to absorb new labor force entrants. Companies are encouraged to meet and exceed their Omanization quotas, turn over management jobs to Omanis, and create training programs for new hires, which can be costly.

Along with Omanization challenges, several outstanding issues are of most concern to U.S. companies:

- Duties continue to be charged on U.S. goods transshipped by road via Dubai despite the agreement in the FTA
- Authenticated certificates of origin/shipping documents are at times still requested by Omani authorities despite not being required or even recognized under the FTA
- Though there has been some recent flexibility in labeling requirements, some companies have reported the requirement to engrave origin markings on products. This can cause product damage and adds costs to the production process.
- Company registration can be slow, especially for consulting companies.

Trade Events

Oman Health Exhibition and Conference 2014

September 5–7, 2016 • omanhealthexpo.com



Pakistan

Summary

U.S. medical equipment and products are traditionally well-received in Pakistan and are known for their quality and longevity. In Pakistan, healthcare is delivered through both the public sector and private sector. The private sector's contribution to healthcare has been growing at a faster pace than government. There are no restrictions on foreign direct investment in healthcare services. Import of medical equipment is allowed under the "Open General" category of the Import regulations, except for Import radioactive equipment that requires prior approval. Customs duty levied on imported products depends on the product classification, for some devices the duty has been brought down from 25 to 5 percent.

The government reserves the power to grant sector-specific duty exemptions, concessions and protections, under Statutory Regulatory Orders (SROs). SROs and Trade policy and regulatory documents are published by the Federal Board of Revenues (fbr.gov.pk).

Pakistani government announced reduction on duty structure on imports of medical equipment. For hospitals planning expansion a concessionary rate of 5 percent customs duty is applicable on imports of medical equipment.

Market Entry

Many foreign manufacturers and suppliers appoint one or more agents/distributors to cover the entire country. At times, foreign principals work through a regional office to cover this market such as Dubai, Singapore, or London. It is comparatively easy to switch agents and distributors in Pakistan without being exposed to legal liability.

Price, quality, and after-sales service support are major factors in medical equipment purchase decisions. Letter of credit is usual the mode of payment for

Statistics

Capital: Islamabad
Population: 190 million
GDP (USD): 246.9 billion (2014)
Currency: Pakistani rupee (PKR)
Language: Urdu, English

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imports. Purchase decision in government follow a tendering process and is time consuming, while it is faster in the private hospitals.

Current Market Trends

A number of trends have emerged in Pakistan, with regard to private sector participation in healthcare. More than 50 percent of both health care financing and actual provision is provided by the private sector. It is also thought that in south Asia, the private sector involvement in healthcare is around 75 per cent.

- The U.S. and Pakistan have a strong bilateral relationship based on a joint commitment to security and stability in the region.
- Domestic production is limited primarily to steel surgical instruments and the majority of the market is supplied by imports.
- The Pakistan medical device market is projected to expand by a 6.3 percent CAGR from 2013–18. This should see it rise from an estimated USD 259.7 million in 2013 to USD 352.0 million in 2018.
- By product area, the performance in CAGR terms from 2013–18 is projected to range from 18.3 percent for orthopaedics and prosthetics to 3.8 percent for patient aids.
- The medical device market is heavily supplied by imports, which account for over 90 percent of the market. In USD terms, imports fell by 13.2 percent in 2012 to USD 250.4 million, compared with USD 288.6 million reported for 2011.
- As with local currency, imports grew each year from 2008–11. In CAGR terms, imports grew by 4.7 percent from 2007–12. By product area, performance in CAGR terms in the 2007–12 period ranged from 21.0 percent for orthopaedics and prosthetics to 1.3 percent for other medical devices. In USD terms, exports grew each year in the 2007–12 period except for 2009 and 2010, when they fell by 8.4 percent and 3.1 percent respectively.
- In 2012, exports rose by 3.5 percent to reach USD 335.9 million. In CAGR terms, exports grew by 3.8 percent from 2007–12. By product area, performance ranged from 36.4 percent for patient aids to negative 12.2 percent for consumables. Surgical instruments make up the bulk of a limited domestic manufacturing sector.

For more information, please visit bit.ly/1ID86ro.

Main Competitors

European, Chinese, Japanese, and South Korean products present U.S. products with stiff competition in Pakistan. Common perception about U.S. goods is that they are expensive and will take longer to reach the Pakistani market. However, U.S. products are viewed as being consistent in terms of quality and are preferred. One concern that has been voiced time and

time again by importers of Medical equipment is that U.S. companies are slow to move in comparison with competitors.

Current Demand

With the number of hospitals, dispensaries, and healthcare units expected to increase owing to the government's plans of expanding the healthcare network, market demand for several kinds of equipment is expected to grow:

- Respirators (HS 9019)
- Monitors and ventilators
- Dental veterinary instruments and appliances (HS 9018)
- Orthopedic appliances and hearing aids (HS 9021)
- X-Rays, and radiography/radio therapy apparatus (HS 9022)
- Second-hand and used X-Ray machines, dialysis machines, and anesthesia apparatus

Public sector expenditures in health facilities are progressive across the country. An amount of PKR 20.48 billion was provided to Health sector in 2014–15 with utilization of approximately PKR 22.4 billion (This includes PKR 10.8 billion as foreign Aid for the Polio Elimination program) by the end of March 2015. Currently Pakistan is spending 0.42 percent of its GDP on health care services. Multiple types of facilities also expect to growth.

- General hospitals
- Specialized hospitals (cancer, cardiac, kidney transplant, liver transplant, dialysis centers, chest diseases, ent, neurology, orthopedic, skin diseases)
- Up-gradation-cum-privatization of government hospitals
- Diagnostics (diagnostic labs, X-Rays, and ultrasonography labs and clinics)
- Fitness centers
- Manufacturing
- Electro-medical equipment

Registration Process

With the dissolution of Ministry of Health, Drug Regulatory Authority of Pakistan (DRAP) and the Ministry of National Health Services Regulation and Coordination are the key regulatory organizations in Pakistan. The Ministry of Health was dissolved in 2011 in order to establish separate Ministries of Health in all the four provinces that are still not active.

In March 2015, The Drug Regulatory Authority of Pakistan (DRAP) notified the Medical Devices Rules 2015, bringing medical devices under comprehensive regulatory control.

The regulation will provide protection against unsafe, non-functional, counterfeit, sub-standard, spurious and fake medical devices and prevent the reuse of disposable devices. Furthermore, promulgation of the rules will avoid illegal route of import.

The rules cover procedures for registration of medical devices and conformity assessment bodies, licensing of establishments, classification and grouping of devices, post-market surveillance, import and export, labeling requirements, advertisement and ancillary matters. The Medical Devices Rules for 2015 can be accessed at bit.ly/1SK7Giu.

Barriers

Inconsistent policies, volatility in political situation also formulate a major challenge or present a barrier to entry for U.S. Companies supplying equipment.

US Companies currently doing business in Pakistan are faced with the issue of getting timely visas for technicians or engineers who need training on the equipment supplied by the U.S. company. It is recommended that all engineers / technicians interested in training and intending on traveling to the US, apply for their U.S. visas three months in advance of the date of travel.

Trade Events

Heath Asia 2015 International Conference and Exhibition

September 8–10, 2015 • Karachi, Pakistan • health-asia.com



The Philippines

Summary

The Philippine medical industry is almost completely dependent on imports, and the medical equipment sector continues to present good opportunities for U.S. companies. The Philippine market is familiar with U.S.-made products, therefore, despite perceived high costs, U.S. products enjoy a prominent place in the market. The U.S. market share of imported medical devices is almost 25 percent. Additional requirements for medical services, new technology, and equipment replacement spur market growth.

Several Philippine investment companies have taken an interest in healthcare and have acquired stakes in the healthcare sector, providing much-needed capital for facilities to upgrade and modernize equipment. Real estate developers have partnered with known healthcare providers to construct health and wellness centers in and around the communities that they are building, adding more appeal to the community and more value to the real estate. In addition to private investments, the government's Public-Private Partnership (PPP) program has allotted PHP 5.69 Billion (Approximately USD 129 Million) for modernization of public hospitals.

Official Department of Health statistics indicate that there are about 1,800 licensed hospitals in the country, of which more than 60 percent are privately owned. Total bed capacity is more than 100,000.

The market is price-sensitive, which explains the growing presence of inexpensive equipment from China and South Korea. Hospitals with limited budget source medical equipment from these countries, and distributors that supply equipment and replacement parts now also carry medical disposables and consumables.

The Philippines hosted a US-government sponsored ASEAN Medical Device Regulatory Harmonization Workshop on June 15–19, 2015. The workshop is a continuing exercise in improving and standardizing the medical device regulatory

Statistics

Capital: Manila
Population: 101.8 million (est. 2015)
GDP (USD): 272 billion (2013)
Currency: Philippine Peso (PHP)
Language: Filipino, English, others

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process in the region. Its ultimate objective is to facilitate the regulatory process for medical device registration in ASEAN member countries.

Market Entry

U.S. suppliers interested in selling in the Philippines should appoint a local distributor, who will handle all aspects of importation including registration, obtaining a license, and getting customs clearance for the products. The local distributor not only helps facilitate the product's entry into the market, but also assumes responsibility for advertising and promotion through sales and dealer networks. He/she registers with the Food and Drug Authority (FDA, formerly the Bureau of Food and Drugs) before operating and receives a License to Import and a License to Operate (LTO) from the FDA.

The average tariff rate for Medical equipment is 3 percent plus a 12 percent value-added tax (VAT). The VAT is based on the valuation determined by the Bureau of Customs for the application of customs duties, plus those duties themselves, excise taxes, and other charges (i.e., charges on imports prior to release from customs custody, demurrage fees, including insurance and commissions).

The Bureau of Customs (BOC) is responsible for customs valuation, classification, and clearance functions.

Current Market Trends

Public hospitals tend to place a greater emphasis on preventive healthcare, while private hospitals concentrate on curative services. Private hospitals have traditionally been equipped with more sophisticated medical equipment due to their larger budgets.


Incidence rates for hypertension and heart diseases, lung and kidney diseases, and other respiratory diseases have remained high. To address the problem, most hospital improvements concentrate on specialized services for radiology, cardiac, lung and kidney examinations, and pathology; thus, demand for ECGs, CT Scans, X-ray and Dialysis machines, and other laboratory instruments should grow.

Main Competitors

The U.S. performs well with high value, low volume medical equipment such as ultrasound equipment, magnetic resonance imaging (MRI) equipment, breathing equipment, and other radiology and electronic medical equipment. U.S. manufacturers, however, face increasing competition from third country suppliers such as China, Singapore, Japan, and Germany.

Current Demand

Besides linear accelerators, electro-cardiographs, ultrasonic scanning machines (ultrasound), magnetic resonance imaging (MRI) equipment, x-ray and radiation equipment, breathing



appliances, and computed tomography apparatus (CT scan) continue to be the most promising subsectors for U.S. manufacturers. There is also a demand for clinical laboratory devices, supplies, and biological test kits.

About 25 public hospitals expect to receive a boost out of the government's Public-Private Partnership (PPP) program. The first beneficiary is the Philippine Orthopedic Hospital, which PPP hopes to transform into the country's primary center for bone and joint diseases at par with global standards.

Requirements for efficient healthcare services, new technology, and equipment replacement drive market growth. All hospitals must continue upgrading facilities to remain competitive.

Some requirements of the hospitals under the PPP program are linear accelerators for eight cancer centers being proposed, dialysis units, various imaging equipment, and devices for treating kidney, heart, respiratory, and diabetes diseases.

Medical device distributors expect from 5–10 percent growth through 2016, which is also when the current administration ends.

Registration Process

Foreign suppliers usually appoint a licensed distributor to represent their interests in the Philippines. Usually, distributors handle all aspects of importation from registration of the products, to obtaining a license and a clearance. Distributors become responsible for the equipment (capability, safety, market performance, and after-sales service) and, thus, prefer exclusive contracts with foreign suppliers.

The Center for Device Regulation, Radiation Health and Research (CDRRHR) was created to oversee the regulation of medical equipment and devices. The Center issues a Certificate of Registration (CPR) for "Registrable" medical products (as described in the FDA website: www.fda.gov.ph). Timeline for a CPR is 180 days. The CDRRHR also issues a Certificate of Exemption (COE) for "medical devices that have not been classified as "Registrable," pending new guidelines for expansion of coverage. The COE is voluntary and usually requested by companies that wish to facilitate release of shipment from Customs, or to participate in bids. The requirements for the Certificate of Exemption include:

- Letter of intent
- Product brochure
- Sample (only when necessary)
- Payment for Certificate of Exemption application fee of 500 pesos (approximately USD 12.00) per product.

A Certificate of Exemption may be obtained in 30 working days; after all required documents have been submitted to and accepted by the CDRRHR.

The foreign company must provide complete documentation for its equipment to the distributor who will register them. Complete and correct documentation determines the outcome of registration and the length of registration process.

Barriers

There are no barriers to the sale or purchase of medical equipment of acceptable international standards.

Trade Events

The first Medical Philippines Exhibition was held in the Philippines in 2014. CS Philippines promotes International Buyer Program events such as Clinical Lab Expo and other Healthcare Team-supported events like Medica.

Poland

Summary

Poland, the sixth largest country in the European Union with a population of 38 million people, represents one of the biggest health care markets in Central/Eastern Europe. That stated, the healthcare sector in Poland has been in a somewhat challenging financial condition of late, and the short-term outlook in the public healthcare sector (the largest sector of health care in Poland) remains tentative.

Since 1999, the Polish health care sector has gone through several unsuccessful attempts at reform. It was expected that the current government will prepare and Parliament will pass major amendments to the existing Health Care Law and Regulations. To date only the new Reimbursement Act has been announced. It has been in force since January 1, 2012. Although it is considered to be revolutionary for the Polish healthcare system, it is still quite controversial. Once the major new healthcare laws become the legal basis as established legislative reform, U.S. Commercial Service Warsaw foresees major opportunities for U.S. companies in the healthcare-medical market. However, it is difficult to make any tangible predictions.

The most common causes of death in Poland are cardiovascular disease (46 percent), cancer (25.3 percent), injuries, poisoning and accidents (6.2 percent), respiratory diseases (5.1 percent), digestive system diseases (4.3 percent), urogenital diseases (1.3 percent), nervous system diseases (1.3 percent), suicides (1.3 percent), and infections (0.7 percent). Also, contagious diseases, especially hepatitis and sepsis, are an important concern. In addition, there is a growing concern with health problems associated with the aging Polish population.

Polish manufacturers are not very competitive because they lack the latest technology, efficient production methods, investment capital, and appropriate marketing resources. Therefore, medical equipment represents a good prospect for foreign suppliers. However, U.S. medical equipment manufacturers face strong

Statistics

Capital: Warsaw
Population: 38 million
GDP (USD): 517.54 billion (2013)
Currency: Zloty (PLN)
Language: Polish

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competition from European companies in particular. EU suppliers increased market share due to their competitive prices as well as availability of EU assistance packages for Poland. Poland imports medical equipment primarily from Western Europe (mainly Germany), the United States, and Asia (Japan and China).

In general, U.S. suppliers of medical products have a good reputation for high quality products. However, technological advantage is not the only factor determining success in the Polish market. Therefore, U.S. companies should focus on educating end-users and other players in the health care sector. A successful exporter should strongly support its agent/representative with marketing strategies.

Market Entry

The medical market in Poland is a relatively difficult market to enter in most cases. Generally, niche and inexpensive products have a greater chance for success. Price is a more important factor than quality in Poland's health care market. The second factor is local availability of service and spare parts. Quality is usually the third element considered by most potential buyers of imported medical devices. Another sale-making factor is quick delivery.

Introducing new products successfully requires a considerable investment in time and expense. Extensive marketing and educational campaigns are recommended for widespread adoption into the marketplace. Polish agents/distributors expect foreign manufacturers to help extensively with marketing expenditures to promote awareness of new products at medical trade shows, seminars and conferences. Operational capital is limited in Poland, even among some larger, more successful Polish suppliers of medical products.

In Poland, medical recommendations are the major source of information on healthcare/medical products and medicines, so a good marketing strategy is to keep doctors well informed about new products. In addition, doctors obtain information from medical conferences and seminars, and expect educated agents/representatives to answer customer questions in order to help them buy the product that meets their needs.

Medical equipment and supplies for the public hospitals are purchased through a competitive bidding process. All tenders are announced in a public procurement bulletin. Private clinics can purchase medical equipment and supplies from any sources they wish or through any trading organization they choose. In spite of the poor financial condition in the health care sector, medical equipment purchases are made but no specific buying pattern has been identified.

Current Market Trends

The latest restructuring of public health care in Poland resulted in establishment of short-term and outpatient facilities. This change required implementation of advanced diagnostic techniques and new surgical procedures that, in turn, created a demand for new equipment. Also, the development of private health care sector in Poland created a need for equipment

not only for general and specialty practice consulting offices, but also for one-day-clinics and private hospitals.

The best prospects for U.S. suppliers are in advanced diagnostic equipment, patient-monitoring systems, surgery equipment (high-tech surgical devices and mini invasive surgery equipment), oncology and nuclear medicine, and cardiovascular surgical devices. The need for medical home-care for the increasing elderly population in Poland also brings prospects for the U.S. medical equipment market. The increasing elderly population reinforces the demand for all kinds of equipment and aid-supplies used by nurses and families for home-care. Also, patient and medical personnel safety is of growing concern to both members of the medical profession and the Polish public. Best sales prospects will certainly focus around assuring stringent personnel safety requirements. This is especially due to the concern regarding hepatitis, sepsis and other contagious diseases. In the near future, prevention should receive similar emphasis considering the present focus on protection.

Main Competitors

The Polish medical equipment market is growing rapidly and in many directions. This is both due to a growing internal market and the companies themselves, which become increasingly competitive and expand to overseas markets. The major export products manufactured by the Polish medical equipment industry include bio-electronic apparatus, operating theatre equipment, rehabilitation equipment, furniture for medical facilities, surgical instruments and devices using medical imaging technologies. One of the most thriving branches of the industry comprises producers of bio-electronic equipment, which is used for vital functions monitoring (patient monitors, defibrillators with the function of monitoring and data transmission, ECG equipment, Holster recorders, and spirometers). Monitoring devices are also offered as network solutions which integrate separate devices into a central monitoring system.

However, imports remain a fundamental component of the local medical equipment market. About two third of all medical equipment used in Poland is imported. Therefore, medical equipment represents a good prospect for foreign suppliers. Though, U.S. medical equipment manufacturers face strong competition from European companies in particular. EU suppliers increased market share due to their competitive prices as well as availability of EU assistance packages for Poland. Poland imports medical equipment primarily from Western Europe (mainly Germany), the United States, and Asia (Japan and China).

Current Demand

According to PMR Research (research-pmr.com), the 2014 Polish medical market registered much slower growth than in previous years. It did not exceed 3 percent and PLN 4.13 billion.

This considerable correction to previous estimates calling for a high annual growth rate in years 2013–16 is linked directly to certain budgetary restrictions and managerial problems

within the Polish public health system including the medical equipment reimbursement regulations, lower number of public tenders, and increase in hospitals' debts.

In Poland, the end-users of medical equipment are the service providers themselves. Service providers include public hospitals (the largest sector of health care in Poland), private clinics, and private doctor's offices. One should take into account the difference between the average patient in a private clinic and the average patient of public hospitals and medical facilities. The public sector receives annual funding for equipment purchases and medical supplies including drugs. Private institutions try to maintain a stock of products based on supply and demand, and generally respond better to a new technology or innovation if it is well marketed.

Registration Process

As Poland is a member of the European Union, import regulations for medical equipment are harmonized with the European Union's Medical Device Directives (bit.ly/1cCGz67), which cover essential safety, health and environmental requirements.

Based on the new approach, rules relating to the safety and performance of medical devices were harmonized in the EU in the 1990s. The core legal framework consists of three directives: Directive 90/385/EEC regarding active implantable medical devices, Directive 93/42/EEC regarding medical devices and Directive 98/79/EC regarding in vitro diagnostic medical devices. They aim at ensuring a high level of protection of human health and safety and the good functioning of the single market. These three main directives have been supplemented over time by several modifying and implementing directives, including the last technical revision brought about by Directive 2007/47/EC. For more details, please visit bit.ly/16MfBUT.

Products manufactured to standards adopted by European standards organizations and published in the Official Journal as harmonized standards, are presumed to conform to the requirements of EU Directives. The manufacturer then applies the CE Mark and issues a declaration of conformity. With these, the product will be allowed to circulate freely within the European Union including Poland.

U.S. exporters should be aware that electrical voltage in Poland is 220 and the current frequency is 50 Hz. Power cables and plugs must be consistent with Polish standards. Labeling and instructions for use (operation manual) must be in Polish language.

Polish distributors and importers of medical devices are required to obtain product declaration or notification with the Office for Registration of Medicinal Products, Medical Devices and Biocide Products (Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Środków Biobójczych, en.urpl.gov.pl).

Barriers

As Poland is a member of the European Union, import regulations for medical equipment are harmonized with the European Union's Medical Device Directives, which cover essential safety, health and environmental requirements. Products manufactured to standards adopted by European standards organizations, and published in the Official Journal as harmonized standards, are presumed to conform to the requirements of EU Directives. The manufacturer then applies the CE Mark and issues a declaration of conformity. With these, the product will be allowed to circulate freely within the European Union.

There are no restrictions in Poland on sales or the importation of used medical equipment by either state-owned or private medical facilities but market opportunities for used medical equipment is relatively small. Medical equipment for the public hospitals is purchased through a competitive bidding process.

All tenders are announced in a public procurement bulletin "Biuletyn Zamowien Publicznych" issued by the Public Procurement Office (bit.ly/1o7h6dz). Private clinics can purchase medical equipment from any sources they wish or through any trading organizations they choose but no specific buying pattern has been identified. Leasing of medical equipment has become more and more popular in Poland, especially among an increasing number of private clinics and private medical facilities.

Trade Events

CEDE

September 2015 • Poznan, Poland • cede.pl/?lang=en

Conference and exhibition for the dental industry sector, held annually.

REHMED-PLUS EXPO

April 2016 • Kielce, Poland • targikielce.pl/index.html?k=rehmed_en

The Trade Fair of Rehabilitation, Therapy, and SPA/Wellness Medical Equipment.

SALMED

April 2016 • Poznan, Poland • salmed.pl/en

Poland's largest event for the healthcare/medical industry sector. Held biannually.

Resources

- Tenders Bulletin, bit.ly/1o7h6dz
- Ministry of Health Tenders, bit.ly/1LPTiGz
- National Health Plan and Programs, mz.gov.pl/en



Portugal

Summary

The Portuguese market for medical equipment is mature and presents a high level of sophistication. The medical device market is projected to expand by a 2013–18 CAGR of 1.7 percent in USD terms and it was valued at USD 976.8 million in 2013. This includes medical devices as well as in vitro diagnosis devices, where the National Health Service represents around ¾ of the total market.

The market for medical equipment has improved in recent years and is expected to present increased business opportunities for U.S. exporters in the future. Prices are considered to be of primary importance in all purchasing decisions, both by the public and private sectors.

Market Entry

In order to enter the medical equipment market in Portugal, U.S. suppliers should be familiar with the EU directives concerning the registration, marketing, and health/safety standards required throughout Europe as well as regulations specific to Portugal. It is therefore advisable to work with a local partner/ distributor. INFARMED is the Portuguese regulation entity responsible for approving the entry of medical devices in Portugal.

Current Market Trends

The Portuguese market for medical equipment is mature and presents a high level of sophistication. Portuguese are educated consumers and expect state-of-the-art medical treatment, which ensures continuous demand for innovative medical equipment and products. One of the prime characteristics of this market is its high level of imports. Total annual expenditures for new equipment are determined in the annual budgets of hospitals. These budgets are prepared according to estimates based on the previous year. The market is very receptive to U.S. products.

Statistics

Capital: Lisbon
Population: 10.8 million
GDP (USD): 243 billion
Currency: Euro (EUR/€)
Language: Portuguese

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A considerable portion of the market is penetrated by foreign products and imports from the United States are considered to be very competitive.

Main Competitors

Some of the major U.S. companies with offices and distribution of their products in the Portugal include GE Medical Systems, 3M, and Johnson & Johnson medical. Siemens and Philips also have a strong presence in the country.

Portugal has approximately 290 companies distributing medical products largely comprised of small or medium-sized companies employing on average 15 to 60 people.

The EU-27 are the major suppliers of medical equipment to Portugal although the U.S. also plays an important role mainly in surgical, dental, imaging/x-ray equipment and optical products.

Portugal has approximately 290 companies distributing medical products largely comprised of small or medium-sized companies employing on average 15 to 60 people.

Current Demand

High quality and technically sophisticated medical equipment has the best market potential in Portugal, especially equipment that increases efficiency and reduces occupancy rates in hospitals. In Portugal, imports are a fundamental component of the Portuguese medical equipment market. Major suppliers are the United States, Germany, France and Japan.

Best prospects include:

- Surgery equipment
- Patient monitoring systems
- Mini invasive surgery (MIS) equipment
- Video endoscopes
- X-Ray equipment
- Digital image processing
- Magnetic resonance imaging (MRI) equipment
- Picture archiving systems

Barriers

There are no significant barriers on U.S. medical devices or products, and the Trans Atlantic Trade and Investment Partnership (TTIP) should facilitate medical device trading between Europe and the United States.

Trade Events

EXPONOR—Feira Internacional do Porto

November 6–8, 2015 • Porto, Portugal • saude.exponor.pt

Resources

- Direcao Geral da Saude (National Policy on Health Technology), bit.ly/1MSD78E
- INFARMED-IP (Regulatory Agency), bit.ly/1IpYH4A
- Administração Central do Sistema de Saúde (ACSS, National Health Technology Assessment Unit), acss.min-saude.pt
- Associação Portuguesa das Empresas de Dispositivos Médicos (APORMED, Portuguese Association for Medical Devices), apormed.pt

Romania

Summary

Healthcare in Romania is dominated by the public sector, which owns most of the hospitals and provides national health insurance to almost all Romanian citizens. Healthcare expenditure was estimated at 4.4 percent of GDP in 2014, below 6.5 percent from GDP as average EU countries.

The public healthcare system includes national health insurance, covering almost all Romanian citizens, as well as a growing and parallel network of private healthcare. According to the Government Program 2013–16, the Ministry of Health is committed to achieving structural reforms in health care to enhance the efficiency, quality and accessibility of the system, especially for the disadvantaged and remote and isolated communities and in the same time to reduce excessive reliance on hospitalization of patients, including improving outpatient services. There are additional opportunities in newly approved projects by the government of Romania in line with the National Health Strategy 2014–20, referring to the two important projects: rural telemedicine and improving health system quality and efficiency.

The market for medical devices, dental products and high technology diagnostic imaging equipment in Romania has excellent prospects for growth. The medical equipment market will continue to grow in the coming years as a result of increased demand, the development of local production, and the need to meet European quality standards and growing imports.

Market Entry

The U.S. companies wishing to enter the Romanian market must refer to the European Union legislation concerning the registration, marketing and safety standards required throughout EU. In addition it is recommended to check as well the national specific legislation that might apply. It is advised to have a local distribution partner. The Romanian market will most likely remain heavily reliant

Statistics

Capital: Bucharest
Population: 21.6 million
GDP (USD): 199.89 billion (2014)
Currency: Romanian leu (RON)
Language: Romanian

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on imports, which are expected to increase due to insufficient high-tech equipment and acute need for renovation within hospitals.

Current Market Trends

Romania ranks the sixth fastest growing market in terms of value in Central and Eastern Europe. Market growth was driven by the macroeconomic improvement and it is forecasted to continue its growth by 3.4 percent annual rate until 2019. The Romanian healthcare industry has high growth potential and there are sufficient human resources providing opportunities for local or foreign investors.

Pharmaceutical sales in Romania in 2015 will grow faster than previously expected due to strong demand for consumer healthcare products. Romania's pharmaceutical market continues to be one of the largest pharmaceutical markets in Southeastern Europe, with pharmaceutical sales of USD 4.28 billion in 2014 (source BMI). The growth in pharmaceutical sales in 2015 would be primarily driven by Romania's improving macroeconomic outlook and the strong demand for consumer healthcare products.

In line with the National Health Strategy 2014–20 in Romania, the overall objective in the health sector is to facilitate access to better and safer healthcare for the general population with particular emphasis on vulnerable groups. Four specific priorities and areas of intervention have been identified, namely: Development of the Health care Infrastructure, Research and Development in the Health Sector, Access to e-Health and Strengthening of Public Health care and Medical Assistance.

According to BMI, the medical device market, estimated at USD 478 million, contracted by 2.5 percent over the 2008–13 period, but it is expected to grow by 2.9 percent over the next three-year period.

According to Business Monitor International the domestic medical device production is estimated to be around USD 150 million, mainly consisting in basic consumables.

Romanian medical device imports value increased by 14 percent reaching USD 441.9 million in 2014. Three products recorded double-digit increases: other medical devices (24.5 percent), patient aids (20.0 percent) and dental products (10.2 percent). The largest product area was other medical devices, worth USD 133.5 million.

During the first trimester of 2015, imports rose in all products areas except for consumables. The best performing product area was other medical devices, followed by patient aids and diagnostic imaging.

In the sector of e-Health the most important projects are developed by the National Health Insurance House (NHIH). There are two projects financed from European Union Funds, E-Prescription and Electronic Health Record, and one self-found which is E-Card. All of these

systems are integrated in the existing centralized SIUI (Sole Integrated Information System) that is implemented at NHIH and CHIH (County Health Insurance House) level. System is operating starting with May 1, 2015.

Main Competitors

Currently, over 100 medical equipment companies are active in the Romanian market, with the most important distributors coming from the US, Germany, Italy, France, Japan, China, Turkey and Switzerland. Among them are big names such as GE Healthcare, Medtronic, Philips, Varian, Johnson & Johnson, Olympus, Nihon Kohden, Greiner, Becton Dickinson, Beckman Coulter, Bioomerieux, Trinity Biotech, and Oxoid.

Current Demand

The newly approved health project will support the 2014–2020 National Health Strategy focusing on three main areas.

Tenders for this health project are forecasted to be launched in September 2015.

Hospital Network Rationalization (USD 249.3 million)

Will finance civil works (within the facilities' current sites/rehabilitation), medical and other equipment, technical assistance, and training.

Ambulatory Care Strengthening (USD 66.4 million)

Will support civil works, technical assistance, equipment, and training.

Health Sector Governance and Stewardship Improvement (USD 13.6 million)

Will finance technical assistance, equipment, communications services, and training.

Registration Process

There are no restrictions on the sales and import of new and refurbished medical devices in Romania. The medical equipment must meet the European certification requirements and have the CE mark. Duties and taxes are applicable at the same rates to both new and refurbished equipment. The key end-user groups for the refurbished category are private hospitals, clinics and specialized ambulatory care segments.

Barriers

For information on existing trade barriers, please see the National Trade Estimate Report on Foreign Trade Barriers (1.usa.gov/115GcP8), published by Office of the U.S. Trade Representative.

Trade Events

DENTA

November 19–21, 2015 • denta.ro/home

International exhibition of equipment, instruments, accessories, materials, and chemical-pharmaceutical products for optical equipment and apparatus.

ROMMEDICA

May 26–28, 2016 • rommedica.ro/home

International exhibition of medical equipment and Instruments.

Resources

- Healthcare Procurement, www.ms.ro/?pag=51
- Public Procurement, e-licitatie.ro
- Government Health Plans, www.ms.ro/?pag=13

Russia

Summary

The Russian medical equipment and supply market is one of the fastest growing sectors of the economy. There is an unsatisfied deferred demand for medical equipment across the country. The Russian government is the largest provider of medical care through a national healthcare system, and hence decides which medical equipment to buy for the country. This fact shapes the demand for medical technology and products.

Market Entry

Companies attempting to enter the Russian market should be willing to:

- Commit time, personnel, and capital, as developing business in Russia can be resource-intensive.
- Conduct market research, such as the CS Gold Key or International Partner Search, to help identify opportunities and potential business partners.
- Conduct due diligence, with actions and programs such as the CS International Company Profile service, to find reliable business partners.
- Consult with U.S. companies already present in the market, as well as with the U.S. Commercial Service and business organizations such as the American Chamber of Commerce in Russia and the U.S.–Russia Business Council.
- Communicate regularly with Russian business partners to ensure common understanding of expectations.
- Frequently travel to Russia to establish and maintain relationships with partners, build rapport, and keep abreast of changing market conditions.
- Maintain a long-term thought process to implement solid-laid plans and achieve positive results.

Statistics

Capital: Moscow
Population: 143 million
GDP (USD): 1.86 trillion
Currency: Russian ruble (RUB)
Language: Russian

Contact

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Current Market Trends

Russian Medical Equipment Market, 2013–15			
(USD Millions)	2013	2014	2015 (proj.)
Total Market Size	6.204	5.097	4.514
Total Local Production	1.034	0.858	0.927
Total Exports	0.094	0.072	0.077
Total Imports	5.263	4.311	3.665
Imports from the U.S.	1.3	1.2	1.008

Source: Korea Medical Devices Industry Association (KMDIA)

Russia instituted a comprehensive reform of its healthcare system, and healthcare is “Priority #1” among the government’s national priority projects. Russia’s healthcare system is rapidly evolving, which is creating many promising areas for U.S. medical equipment exports. It is currently estimated that only 20 percent of the Russian population of 142 million has access to quality healthcare. The majority of hospitals and polyclinics are public and belong to federal, regional, or local governments.

At the moment, the two major sources of public healthcare funding—mandatory insurance funds (30 percent) and spending supported by federal and regional budgets (70 percent)—do not cover all healthcare expenses. As a result, a significant portion of overall (public and private) healthcare spending (about 20 percent) is covered out of the patients’ pockets. Voluntary healthcare insurance programs account for approximately one-third of total private healthcare expenditures. According to long-term reform plans, mandatory insurance funds will serve as the main source of healthcare funding and should provide transparency and control over cash flow within the system.

According to Healthcare through 2020, a document developed by the Ministry of Healthcare and Social Development, Russian citizens will begin to receive higher quality medical care which will be standardized throughout Russia. It states that there will be new and effective medical procedures introduced and that new medical equipment will be supplied to institutions. However, there are significant downward pressures on the Russian government budgets and it remains to be seen whether these goals will be reached. Russia has joined the WTO, which should lower tariffs for medical equipment from the present 15 percent to between 0–7 percent.

Currently, almost two-thirds of the medical equipment and devices being used in public clinics and hospitals are obsolete and need replacement. There are two major issues that the Russian healthcare system faces; Healthcare facilities are in very poor condition. According to data from the Russian Federal Statistic Service, 2 percent of medical facilities are in hazardous condition, 8.5 percent do not have cold and hot water, 32.5 percent do not have hot water,

more than 10 percent do not have central heating, 11.2 percent do not have a sewage system, and 6.7 percent do not have telephone connections. In order to solve these problems, the regional parts of the budgets allocated for modernization will be used. Secondly, new medical equipment terribly needed for those medical facilities to be brought up to par—a positive factor is that this will drive the demand for medical equipment.

The Russian government is aggressively seeking to increase the amount of medical equipment manufactured by Russian producers. Specifically, foreign manufacturers of medical equipment currently selling to the Russian government are strongly encouraged to “localize” production for medical devices and pharmaceuticals. If a company fails to demonstrate a sufficient percentage of local content, it may be disadvantaged in Russian government tenders or disqualified altogether. Previously, the Russian government had accepted packaging of products in Russia as meeting a minimal requirement for local content. However, that understanding will expire in 2015 after which the GoR will require more substantial investment in manufacturing or research and development. Foreign medical device and pharmaceutical companies have expressed that meeting these requirements will be highly disruptive, challenging, and perhaps not commercially viable.

Russian government organizations are the main users of medical equipment; approximately 80 percent of medical equipment is sold to them. Private hospitals and patients represent the other 20 percent. Because of that uneven distribution, government procurement programs (“tenders”) play a crucial role in this market but are difficult to gain access to bid on them.

Main Competitors

According to several sources, imported medical devices constitute 60 percent of the Russian market. Statistical data show that 40–45 percent of imports come from Germany, 20–25 percent from the United States, 10 percent from Japan, and 5 percent each from Italy and France. For the last three years, a growing number of cheap analogs from China and Pakistan have entered the Russian market in large volumes.

Current Demand

Russia is still dependent on imports for a significant number of medical equipment industry subsectors, especially those requiring large investments in research and development (Research and development), innovative technologies, and automation. The most promising market segments include diagnostics and visualization, cardiovascular, ophthalmology, orthopedics, laboratory diagnostics, and urology equipment and technology.

Registration Process

All medical equipment manufactured in Russia or abroad needs to be registered and certified in order to pass through customs, be sold, and used in Russia.

Required documents include a Registration Certificate, issued by the Federal Service of Health Care and Social Development Control and valid indefinitely. It act as permission for the product to be introduced to the market. Establishes the OKP code (Russian product classification system), in accordance with which the VAT rate is determined for customs clearance of the product—either 0 percent or 10 percent (the standard VAT rate is 18 percent);

Companies should treat seriously threats to Intellectual Property and take steps to protect their IPR. Existing Russian legislation, when adequate, is not enforced effectively or consistently.

Before starting the process of registration, a manufacturer of medical equipment should keep in mind that the process itself is costly and complicated since the regulatory procedures continuously change and are written only in Russian. It is highly recommended that U.S. companies work through a Russian representative, subsidiary, Russian distributor, or a specialized consulting company to navigate this difficult process.

Barriers

Despite positive changes in the last several years, the medical standards regime in Russia still lacks transparency. FDA approval is not accepted here and Russia continues to rely on product testing as a key element of the product approval process. Other types of product safety assurance, such as plant auditing, quality systems, and post market vigilance are still underdeveloped. Russia continues to follow redundant practices for the testing of internationally accepted certified products, which can delay the entry of products into the country. Problems with customs can also be a factor here.

Trade Events

Zdravookhranenie

December 7–11, 2015 • Moscow, Russia • zdravo-expo.ru/en

International exhibition of medical equipment and drugs.

Saudi Arabia

Summary

Healthcare and education remain top priority for the Saudi government, representing about 44 percent of government spending. Budgeted expenditures for the healthcare and social affairs sectors in 2015 were set at USD 42.67 billion, a huge 48 percent growth over 2014 figures. Health care expenditures and delivery is dominated by the public sector, with government spending representing almost 79 percent of total spending on this sector, estimated at USD 20 billion annually.

The Saudi health care sector is still the largest in the Near East North Africa; the latest available figures indicate that the Saudi market for medical devices stood at USD 1.72 billion in 2013, and was expected to have reached USD 1.88 billion in 2014, more than nine percent average annual growth. Imports account for more than 92 percent of the market at USD 1.59 billion, and U.S. companies command the list of suppliers with a 21 percent share of total imports. Local manufacturing is still limited to consumables including bandages, gloves, syringes, and some furniture including non-electrical beds.

Hospitals in Saudi Arabia are among the best equipped in this region and the Ministry of Health set aside an annual line item figure for "Replacement of Medical Equipment."

The Saudi pharmaceutical market is one of the largest in the Near East with expenditures reaching USD 4.5 billion in 2014 and expected to grow an average of 7 percent annually. Unlike other countries that prefer generics, patients in Saudi Arabia favor branded since most medicines can be acquired without a doctor's prescription, as such consumers can easily exercise their preference for branded medicines. The 2015 budget included the construction of new primary care centers, 11 new hospitals, two medical cities and about 20 medical centers and polyclinics.

Statistics

Capital: Riyadh
Population: 29.9 million (est. 2014)
GDP (USD): 777.9 billion (2014)
Currency: Saudi riyal (SAR)
Language: Arabic (official)

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Market Entry

Although one hundred percent foreign ownership is allowed, it is advisable that U.S. companies designate a local agent/representative to conduct business in Saudi Arabia. It is also advised that companies work with local legal counsel when drawing up a contractual agreement. Shari’a courts are the courts of general jurisdiction in the Saudi judicial system, and these courts review all foreign court decisions to ensure consistency with Shari’a law.

Medical equipment is charged a 5 percent customs duty; in some instances, however, imported equipment is exempted, notably if the shipment is bound for a government entity and/or a government project.

Current Market Trends

Based on data from industry and the World Health Organization (WHO), Saudi Arabia, like other countries in the Arabian Gulf, continues to exhibit lifestyle change trends within its morbidity statistics. Non-communicable diseases, such as diabetes, cardiovascular diseases and cancer have become the main causes of death, estimated to account for 78 percent of total deaths. Additionally, the Kingdom has one of the world’s highest rates of traffic accidents, which in 2012, resulted in 5,200 deaths.

In turn, those figures have been the key drivers for various equipment and services, namely:

- Emergency and trauma equipment
- Rehabilitation equipment
- Diagnostic equipment
- Electro-medical equipment
- Hospital beds
- Orthopedic appliances and prosthesis
- Dental equipment
- Laboratory equipment
- Hospital operation and management
- E-Health
- Generic pharmaceuticals

Moreover, the Kingdom was recently hit by the Middle East Respiratory Syndrome (MERS) virus with some 282 people dying from it. Lifestyle changes have created additional pressure on available resources and demand for the health care system, in general, lacks behind in the number of physicians, nursing, and technical staff.

WHO data revealed that 20 percent of nationals over the age of 20 suffered from type-2 diabetes, 35 percent of Saudi adults are obese, and more than 6.5 percent of the populations has high blood pressure.

The public sector dominates the supply of health care services in Saudi Arabia and account for the majority of health care expenditures. The public health care sector approximately represents 79 percent of bed capacity. Industry sources expect the government sector to outpace the private sector in the level of investments and beds capacity. The latest figures suggest that the MoH bed capacity will almost double to 73,768 beds by 2020, the private

sector will add 13,875 beds raising its capacity to 26,000 by 2020, while other government organizations will total 20,000 beds in 2020.

The Saudi government's 10th five-year development plan (2015–19) stipulates:

- Improving emergency medical services
- Improving SFDA control and supervisory services
- Enhancing the application of cooperative health insurance
- Provide training and developing the skills of workforce
- Improving the performance efficiency of management and operation systems
- Improving healthcare services for the special-needs groups
- Reviewing the regulations related with medical malfunctions and violations
- Improving healthcare safety
- Encouraging health establishments to obtain international accreditation.
- Establishing more primary health care centers and specialized curative services
- Improving the quality of health services provided to children, the aged and the disabled, and expanding home health care for the aged and disabled persons
- Increasing the role of the private sector in provision of health services and expanding the scope of medicines and medical appliances manufacturing
- Enhancing the e-health system and the supporting information systems, and expanding the scope of their use
- Developing the preventive and curative health services provided to pilgrims and Omra performers and ensuring Haj seasons free of diseases and epidemics

Main Competitors

The Saudi market is completely dependent on imports for medical devices; while U.S. suppliers enjoy some advantages, including competitive prices, language, and exchange rate. European suppliers are aggressively gaining market share with their close proximity to the market and perceived better customer support.

On the other hand, the pharmaceuticals sector is characterized by a growing domestic manufacturing base, mainly for generic and OTC drugs, as well as licensing arrangements with branded research-based foreign innovative drug manufacturing companies.

The Saudi domestic pharmaceutical industry lacks Research and development capabilities, and it remains focused on producing basic formulations of off-patent preparations to feed into the generics market. The lack of Research and development is compounded by an unpredictable IPR regulatory system and, recently a vague pricing structure, which is affecting the introduction of many new research-based products into the market.

Government policies favor domestic producers, providing them with exemptions, including interest-free funding, subsidized utility charges, and no import duties on raw materials and

intermediate products. Industry sources expect domestic production to grow to USD 1 billion in 2014, accounting for about 20 percent of the total pharmaceutical market.

Current Demand

Total health care expenditures in 2015 are expected to remain at 2014 levels (nearly at USD 20 billion), due in part to lack of public funding for previous and ongoing projects, as well as changes at the Ministry of Health administration (including a new Minister). The demand for health care services has continuously outpaced supply and both the public and private sectors are struggling to accommodate growing demand. A growing population, compulsory health insurance coverage, and the prevalence of diseases are serving to boost the demand for services and hospital bed occupancy. Today, the overwhelming majority of Saudi Arabia's 8.5 million health insurance holders are expatriates. The insurance reform could swell the pool with more than a million Saudi civil servants plus about five million dependents.

New projects in the 2015 MoH budget included the construction of three hospitals, three blood bank centers, 11 primary health care centers, and 10 comprehensive care clinics. Hospital beds currently exceed 64,000 for all hospitals in Saudi Arabia, expected to grow to 119,000 beds by 2020. Moreover, a private group of investors is developing Riyadh's Medical Village over a 250,000 sq. m. area, consisting of eight 130-bed hospitals, 60 outpatient clinics, and other amenities and services.

Additionally, the Executive Board of the Health Ministers' Council for the GCC states (HO in Riyadh) release an annual tender valued for a couple of billions of dollars for:

- | | | |
|---------------------------------|-------------------------------|----------------------------|
| • Hospital sundries | • Rehabilitation | • Medicines |
| • Renal Dialysis supplies | • Cardiovascular | • Vaccines |
| • Oral and dental care | • Linens and medical uniforms | • Chemicals |
| • Laboratory sundries | • Ophthalmology sundries | • Insecticides |
| • Orthopedic and spinal surgery | • ENT sundries | • Radio-pharmaceuticals |
| | | • Renal dialysis solutions |

Major players in the Saudi health care sector include (by expenditures):

- | | |
|---|--|
| • Ministry of Health | • Ministry of Interior |
| • Saudi Arabian National Guard | • Royal Clinics |
| • Ministry of Defense and Aviation | • John Hopkins Aramco Healthcare |
| • Ministry of Higher Education | • Private Sector |
| • General Organization for Social Insurance | • GCC State Health Ministers Council Executive Board |

Registration Process

The Saudi Food and Drug Authority (SFDA) monitors and controls the import and distribution of medical devices, pharmaceuticals, and food products. For medical devices, the SFDA will usually accept, register, and authorize the marketing and sale of any device that complies with applicable provisions of the SFDA's Interim Regulations and relevant regulatory requirements applicable in one or more of the countries of the Global Harmonization Task Force (GHTF), which includes Australia, Canada, Japan, USA, and EU/EFTA. More information on the registration process can be found at sfda.gov.sa/en.

Barriers

Commercial Dispute Settlement

There is not yet a transparent, comprehensive legal framework in place for resolving commercial disputes. Saudi commercial law is still developing, but in 1994 the Saudis took the positive step of joining the New York Convention of 1958 on the Recognition and Enforcement of Foreign Arbitral Awards. Saudi Arabia is also a member of the International Center for the Settlement of Investment Disputes (also known as the Washington Convention). However, dispute settlement in Saudi Arabia continues to be time-consuming and uncertain. Even after a decision is reached in a dispute, effective enforcement of the judgment can still take years. Generally, the Board of Grievances has jurisdiction over disputes with the government and over commercial disputes.

In October 2007, King Abdullah issued a royal decree to overhaul the Kingdom's judicial system, including allocating SAR 7 billion (approximately USD 1.9 billion) to train judges and build new courts. The decree establishes two Supreme Courts, a general court and an administrative court, and specialized labor and commercial tribunals, although implementation has been slow.

Business Visas

All visitors to Saudi Arabia must have a Saudi sponsor in order to obtain a business visa to enter Saudi Arabia. Business visitors and foreign investors can apply through the Saudi Arabian General Investment Authority (SAGIA) for a visitor visa at the Saudi Embassy or Consulates in the United States.

Saudi Arabia has also begun to implement a decree stating that sponsorship for certain business visas is no longer required. Based on new instructions, the issuance of a visitor's visa should be affected within 24 hours from the application date.

While most business visas are valid for only one entry for a period of up to three months, the Saudi Embassy in Washington has begun issuing a 5-year multiple entry visa for selected business people, taking into consideration the principle of reciprocity. Finally, the Saudi

Ministry of Foreign Affairs is currently examining the issuance of a visitor's visa at ports of entry for selected nationalities.

Delayed Payments

Payment delays are on the rise in the wake of lower oil prices, according to some members of the business community. Some companies carry Saudi government receivables for years before being paid. The government appears committed to clearing remaining arrears, but the problem persists. U.S. companies should check with the U.S. Embassy or Consulates if a problem arises.

Intellectual Property Protection

Saudi Arabia recently undertook a comprehensive revision of its laws covering intellectual property rights to bring them in line with the WTO agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs). The Saudi legal system protects and facilitates acquisition and disposition of all property rights, including intellectual property. The Saudi government recently updated the Trademark Law (2002), the Copyright Law (2003), and the Patent Law (2004), with the dual goals of TRIPs compliance and effective deterrence against violators. In 2008 the Violations Review Committee created a website and has populated it with information on current cases. The government also endorsed the country's joining the "Paris Convention for Protection of Industrial Property" and the "Berne Convention for the Protection of Literary and Artistic Works." Although intellectual property protection has steadily increased in the Kingdom, intellectual piracy remains a problem.

The current Law on Patents, Layout Designs of Integrated Circuits, Plant Varieties and Industrial Designs has been in effect since September 2004. Largely due to a lack of adequate resources and technical expertise, when this law went into effect the Patent Office had issued just over 40 patents and had a large backlog (more than 9,000 applications dating back to issuance of Saudi Arabia's first patent law in 1989). The office has since streamlined its procedures, hired more staff, and reduced this backlog. Protection is available for product and product-by-process. The term of protection was increased from 15 years to 20 years under the new law, but patent holders can no longer apply for a routinely granted five-year extension.

Trademarks are protected under the Trademark Law. The Rules for Protection of Trade Secrets came into effect in 2005. Saudi Arabia has one of the best trademarks laws in the region, but enforcement still lags and procedures are inconsistent.

The Saudi government has revised its Copyright Law, is devoting increased resources to marketplace enforcement, and is seeking to impose stricter penalties on copyright violators.

The Saudi government has stepped up efforts to force pirated printed material, recorded music, videos, and software off the shelves of stores. These efforts included stepping up raids on shops selling pirated goods in 2008. However, many pirated materials are still available in the marketplace. An Islamic ruling, or fatwa, stating that software piracy is "forbidden" backs

enforcement efforts. Following successful “out-of-cycle reviews” in 2009, Saudi Arabia was removed from the Special 301 Watch List in February 2010.

Saudi Arabia has not signed and ratified the WIPO internet treaties.

Counterfeiting

Manufacturers of consumer products and automobile spare parts are particularly concerned about the widespread availability of counterfeit products. Anti-counterfeiting laws exist, and the U.S. government has urged the Saudi authorities to step up enforcement actions against perpetrators. In some popular consumer goods, manufacturers estimate that as much as 50 percent of the entire Saudi market is counterfeit.

In order to restrict the entry of counterfeit products, the Saudi Customs Authority recently implemented a new directive requiring all imported goods to clearly display the “Country of Origin” or “Made in ...” on the items in an irremovable manner either by engraving, knitting, printing, or pressing based on the nature of the imported items. This requirement is strictly enforced.

Arab League Boycott

The Gulf Cooperation Council (Saudi Arabia, Kuwait, Bahrain, Oman, Qatar and the United Arab Emirates) announced in the fall of 1994 that its members would no longer enforce the secondary and tertiary aspects of the Arab League Boycott. The primary boycott against Israeli companies and products still applies. Advice on boycott and anti-boycott related matters are available from the U.S. Embassy or from the Office of Anti-Boycott Compliance in Washington, D.C.

Government Procurement

Government contracts on project implementation and procurement strongly favor Saudi and GCC nationals. However, most Saudi defense contracts are negotiated outside these regulations on a case-by-case basis. Saudi Arabia published its revised government procurement procedures in August 2006. Foreign suppliers participating in government procurement are required to establish a training program for Saudi nationals. However, the SAG has yet to initiate accession procedures to join the government Procurement Agreement, as agreed during the Kingdom’s accession process to the WTO. In addition, Saudi Arabia gives priority in government purchasing to GCC products. These items receive up to a 10 percent price preference over non-GCC products in all government procurements in which foreign suppliers participate.

Shipping

Saudi Arabia gives preference to national carriers for up to 40 percent of government-related cargos. Two local companies take full advantage of this situation.

Standards and Labeling

As part of the GCC Customs Union, the six Member States are working toward unifying their standards and conformity assessment systems. However, each Member State continues to apply its own standard or a GCC standard. A new ICCP mandates that a Certificate of Conformity must accompany all consumer goods exported to Saudi Arabia. Labeling and marking requirements are compulsory for any products exported to Saudi Arabia.

Trade Events

C3 Saudi International Healthcare Forum

April 25–27, 2016 • Riyadh, Saudi Arabia

Healthcare themes and issues. Drawing on high level officials and executives from both the public and private sectors in the U.S. and Saudi Arabia.

Saudi Health Exhibition and Conference 2016

May 16–18, 2016 • Riyadh, Saudi Arabia

Showcasing the latest products, technology, and services. This is the only event with the full support of the Ministry of Health, and will cover the full spectrum of healthcare.

Resources

- Saudi Ministry of Health, moh.gov.sa/en
- Executive Board of the Saudi Health Ministers Council, sgh.org.sa/en-us/home.aspx



Singapore

Summary

According to the World Health Organization (WHO), Singapore's healthcare system ranks sixth globally and offers the fourth-best healthcare infrastructure in the world. It also serves as the healthcare and medical hub of the region and is arguably Asia's best healthcare system. Demand for healthcare in Singapore is set to grow as the population increases and ages. The island state's population is likely to increase to 5.5 million by 2020. Demand for state of the art medical technologies is also expected to grow as Singapore strengthens its reputation as the region's healthcare hub and center for healthcare excellence offering first class healthcare delivery systems and facilities to both its resident population and the international patient market.

Singapore serves as a showcase for healthcare delivery and medical technology and is considered the gateway to the regional economies of South East Asia. The three key healthcare strategies Singapore is pursuing are clinical research, improving long-term care and moving towards more sophisticated care.

Singapore recently implemented universal healthcare called "MediShield Life, a universal insurance coverage. Under MediShield Life, even people with pre-existing conditions will be covered. The national healthcare plan covers 100 percent of the population and ensures that Singaporeans all have access to medical care.

Market Entry

U.S. companies who are new to the market and interested in exporting to Singapore may consider appointing a local distributor to represent their company's product and services. Given the small market size of the island state, most potential distributors would request exclusive rights to sell the product. They will also likely ask for distribution rights for the regional South East Asia countries as Singapore serves as a gateway into the region. U.S. exporters of medical

Statistics

Population: 5.47 million
GDP (USD): 307 billion
Currency: Singapore Dollar (SGD)
Language: English (business);
Mandarin, Malay, Tamil

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equipment should evaluate the suitability of the distributor based on the company's contacts in the market, their product range and whether their products complement that of the U.S. company. As the sales in the local market increases, the U.S. company can look into setting up an on-going presence in Singapore much like how some large MNCs have set up regional offices in Singapore. This brings the U.S. company closer to their customers, demonstrates their commitment to the region and allows for prompt and enhanced customer service.

Current Market Trends

Singapore's public hospitals and specialty centers engage in clinical research with the many pharmaceutical, biotechnology and medical technology companies based in Singapore. Singapore's goal is to become Asia's premier healthcare hub via the attraction of foreign patients. There is also an emphasis towards a healthy lifestyle and a focus on preventive care.

Doctors here are also pushing ethical and professional standards, and it is expected that every major hospital in Singapore will have attained the widely recognized American mark of quality health care. Already, the majority of private and public sector hospitals have been accredited by the Joint Commission International (JCI), the overseas arm of the United States' main hospital accreditation agency.

Singapore represents a good market for the introduction of more advanced health IT systems. Singapore has an overwhelming presence of 3G and 4G services which make the adoption of advanced mobile health and telehealth technologies less challenging than other markets. Some home-based outpatient mobile health and telehealth initiatives are already in place. Several public hospitals use a transitional healthcare model whereby medical staffs visit patients at home to ensure that these patients adhere to their medicines regimes. This initiative presents a market opportunity for health IT programs to alleviate the strain on healthcare personnel.

Main Competitors

Major competitors of the U.S. are medical devices from Germany, other European economies, Japan and Australia. Local production by multinational corporations and indigenous Singapore companies is primarily for export or contract manufacturing.

Current Demand

Singapore's healthcare services are comparable to those of other industrialized nations. The plan is to raise health spending to reach USD 1.37 billion (SGD 2 billion) a year in the next five years. The Singapore government is focused on moving up the value chain by building up services that assist research and healthcare delivery in Singapore and the region. A total of 23 hospitals and six specialty centers, provide a complete spectrum of clinical services from basic health screening to complex quaternary care.

Registration Process

Medical devices are classified under four risk classes. All medical devices, except Class A devices, must be registered with the Singapore Health Sciences Authority prior to placing them on the Singapore market. Only Class A devices supplied in a non-sterile state is exempted. Classification of medical devices will depend on a series of factors and these include how long the device is intended to be in use; whether the device is invasive, implantable, active or if it contains a drug or biologic component. The classification rules are adopted from guidance developed by the Global Harmonization Task Force. For more information, visit bit.ly/1fEBxfA.

Barriers

There are no barriers to entry as Singapore is an open economy and a firm believer in keeping trade open. There are no custom duties on medical devices. A 7.0 percent goods and services tax (GST) is imposed on all goods sold and services provided, locally. Imports are subject to GST, but payments are refundable on re-exports.

Trade Events

BioPharma Asia Convention 2016

March 22–24, 2016 • Singapore • terrapinn.com/exhibition/bio-asia

Asia's leading biopharma industry event. Focus on human health and social work activities, drug discovery, and manufacturing.

MEDLAB Asia Pacific 2016

March 22–24, 2016 • Singapore • medlabasia.com

Singapore's largest laboratory conference and exhibition.

IDEM 2016 (International Dental Exhibition and Meeting)

April 8–10, 2016 • Singapore • www.idem-singapore.com

The leading dental trade fair in the Asia-Pacific region. More than 230 exhibitors and over 6500 visitors from approximately 56 countries are expected.

Medical Fair Asia 2016

August 31–September 2, 2016 • Singapore • www.medicalfair-asia.com

One of Asia's leading and most established trade fairs focused on equipment and supplies for the hospital, diagnostic, pharmaceutical, medical and rehabilitation sectors.

Slovak Republic

Summary

Slovakia's market size is similar to Hungary or in per capita terms to Spain. Slovakia is compliant with international requirements for approvals as well as intellectual property protection. The country has a tradition of medical device manufacturing, but it is increasingly difficult for domestic production to compete with Western quality and innovative imports. As of December 2014 the debt of Slovakia's health-care system generated mainly by the State hospitals was EUR 436 million (USD 493 million).

Market Entry

Slovakia is one of the more developed health device and pharmaceutical markets in the Central and Eastern European region. In Slovakia, Euro zone membership has made trade with Slovakia easier by providing more transparent pricing and greater currency stability. A foreign producer that would like to export medical devices into Slovakia must first establish a contract with a local importer, who can help the company fulfill regulations such as the CE mark, Declaration of Conformity, translation of directions and manuals into Slovak, and a guarantee that the product has been approved by the Ministry of Health. Medical devices and pharmaceuticals are subject to a customs duty and value added tax (VAT) of 20 percent. Some products carry a 10 percent VAT.

Current Market Trends

According to Market Research Reports, Inc. (marketresearchreports.com), the Slovak medical device market is expected to grow by 3.9 percent over the 2013–18 time period, as the economy grows and health spending remains high. In 2013, the Slovak medical device market was estimated at USD 545 million (USD 100 per capita) and should reach USD 659.9 million (USD 121 per capita) by 2018.

Statistics

Capital: Bratislava
Population: 5.41 million
GDP (USD): 97.71 billion (2013)
Currency: Euro (EUR/€)
Language: Slovak

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In 2013 (2014 data not yet available) 58 percent of overall medical aids and special medical materials costs (representing 68 percent in units) were the reimbursable medical aids and special medical materials. 37 percent (representing only 21 percent in units) were hospital medical aids and special medical supplies. Only 5 percent (representing 10 percent in units sold) were over the counter/no prescription medical aids.

According to the Slovak National Information Center, in 2014 Slovaks consumed 84 million packs of drugs out of which 57. percent were prescription drugs reimbursed by health insurance companies in the amount of EUR 825 million (USD 932 million) and co-paid by patients in the amount of EUR 140 million (USD 158 million). Analgetics, anti-rheumatics and antiflogistics are the TOP three over the counter drugs. In 2014 over the counter drugs sales amounted EUR 148 million (almost USD 167 million). Annually about 100 tons of unused/ expired drugs (excluding those being disposed of in households) are returned to pharmacies.

Due to domestic legislation which allows pharmacies to sell medicines back to distribution companies, Slovakia has been facing problems with drug trafficking. Experts estimate that drug sales in Slovakia amount to about EUR 1 billion (USD 1.13 billion) annually, with re-exports representing EUR 300 million (USD 339 million) and mainly targeting the German, Czech and Scandinavian markets. In order to decrease the parallel trade in drugs plaguing the country, Slovakia as the only country in the European Union started banning the re-export of medicines. In 2014 The Slovak State Institute for Drug Control banned 28 types of drugs (usually prescription ones covered by health insurance) in almost 86,000 packages to avoid shortages. To this day 322 drugs have been banned. This legislation however is currently being examined by the European Commission.

In 2013 pharmaceutical companies spent EUR 41 million (USD 46 million) on marketing and promotion.

Launch of Diagnoses Related Groups (DRG) classification system and E-Health project (electronic services in health care) remain Slovakia's priority. The Ministry of Health of the Slovak Republic launched a competition over software components for the National Health Information System worth EUR 40.25 million (USD 45.48 million, to be financed from the EU Operational Program Digitalization of Society) last summer. Because of a complaint submitted by an unsuccessful bidder in the competition (currently under scrutiny by the Slovak Public Procurement Office) the ministry cannot sign an agreement with the winner and the implementation is delayed by two years till 2017.

Meanwhile, after a five year postponement, the ministry announced a test version with selected hospitals, medical practices, pharmacies and one laboratory to be launched by the end of this year. Patients should be included after the testing is evaluated, preliminary in the beginning of the year 2017. So far the E-health project contracts reached EUR 47 million (USD 53.1 million).

Ministry of Health of the Slovak Republic continues plans to erect a new hospital as a part of the BioMedPark project. The cabinet approved a feasibility study on June 11, 2014 moving Slovakia's very first health care sector PPP project from the preparatory to the implementation phase. Projecting 30 years of service, the total revenues of the project is estimated at EUR 6.3 billion (USD 7 billion). BioMedPark project includes the construction of university hospital (with capacity of 945 beds securing 44,000 in-patients annually), bio-medical scientific park of the Slovak Academy of Sciences, new premises of the Medical Faculty and the Pharmacy Faculty of Comenius University. The private investor could be chosen by the end of 2015 and construction might be completed with a full year delay in 2017. The current price tag is EUR 220–250 million (USD 248–282.5 million) contrary to the original construction cost estimated at twice as much. According to media resources daily there are seven contestants interested in the procurement.

Inspired by foreign countries Ministry of Health of the Slovak Republic plans to build integrated health care centers in 140 Slovak municipalities. Centers should provide social services aside from housing general practitioners, gynecologist and dentists. This initiative is calculated at EUR 280 million (USD 316 million) and should be financed by Brussels. First centers are expected to operate in 2017.

Since revision doctors and doctors executing treatments have different opinions on treating certain diseases (e.g. hypertension, pre-operation treatment, perinatal bleeding, osteoporosis) insurance companies refuse to reimburse payments to hospitals in particular those that could have been executed by ambulatory treatment or in the form of individual treatments. Due to missing State standardized control procedures and guidelines, e.g. VŠZP focused last year on effective use of medical aids used for chronic wounds treatments. In case of a positive control finding, ambulatory financial penalty ranged from EUR 3,000–5,000 (USD 3,390–5,650). Fictive treatments, pharmacies bartering with medical prescriptions and so called “flying doctors” (doctors with multiple contracts) have also been subject to control.

Prime Minister Robert Fico is looking for state budget funds to acquire private health insurance companies Dôvera and Únia. Both companies insure about one-third of the Slovak population and their estimated market price is EUR 650 million (USD 734.5 million). The plan is to unify the country's private and public health insurance funds into a single state-owned insurer. There is likely to be a lengthy negotiation and a legal battle before this is realized.

Slovak basic hospital network consists of 78 hospitals, out of which 67 are members of The Slovak Hospital Association. Domestic and international experts believe 30 hospitals are optimal. The rest should gradually transform into specialized hospitals, one day surgery facilities, after treatment facilities, sanatoriums, clinics or first aid service stations. Profiling the new basic hospital network is based on defining various criteria (inhabitants' perimeter, accessibility within certain time, amount of hospitalizations, and current bed conditions). Different views and expertise on criteria outline slow down the ongoing reform. EUR 113 million (USD 128 million) is the annual investment costs into Slovak medical facilities.

European Commission has agreed to support the hospital restructuring and cover 1/3 of these costs. The rest should come out of the Slovak State budget and PPP projects. The ministry's ambition is to launch hospitals' stratification by the end of 2015 through the first tender to draw EU funds preferably in the Trenčín self-governed region.

In March 2015, Kosice self-governing region and the company Svet zdravia started erecting a new generation hospital in Michalovce, Northern Slovakia. The cost of the investment was estimated at EUR 34 million (USD 38.4 million) and the project is planned to be completed in early 2018. Svet zdravia which belongs to the Penta financial group already operates 12 hospitals, with an additional two needing approved by the Slovak Antimonopoly Office. Penta is the dominant private entity of the Slovak healthcare.

Main Competitors

Slovakia's medical device manufacturing sector is skilled, yet still remains small. Thus, most of the Slovak medical device market is dominated by imports mainly from the U.S. and European Union markets. Around 88 percent of the medical device market is supplied by imports out of which Germany and the U.S. account for almost 50 percent of all imports. In the twelve months leading up to January 2015 medical device imports fell by 1.7 percent to USD 497.4 million (while 2008–13 compound annual growth rate of medical device imports was 1.5 percent).

Local producers focus a large part of their resources on export markets such as the Czech Republic, especially in dentistry. Domestic medical device production is estimated to be in excess of USD 300 million.

There are 284 companies (out of 294) selling pharmaceuticals that cover 43.7 percent of the local market. U.S. pharmaceutical companies, e.g. Abbott, Amgen, Johnson & Johnson, Merck and others, have a 30 percent market share. According to 2014 turnover, the largest pharmaceuticals companies in Slovakia are Novartis, Sanofi-Aventis Slovakia, Glaxo Smith Kline Slovakia and Roche.

In Slovakia, there are 17 licensed pharmaceutical distributors, the biggest one being Phoenix (38 percent market share) and Unipharma (30 percent market share). Medications are sold by and through 2,230 pharmacies (the number of pharmacies increased by 427 between the 2010 and 2015). Dr. Max with 208 pharmacies and Domov Zdravia also with 200 pharmacies are the biggest pharmacy networks, followed by SunPharma with 48 pharmacies.

Current Demand

Slovakia has excellent market opportunities in the fields of sophisticated health technologies and equipment, dental care equipment and many other devices that increase efficiency and reduce occupancy rates in hospitals.

Leading exports from U.S. to Slovak Republic, 2013–14			
(USD, September through September)		2013	2014
9026	Inst Etc Measure Or Check Flow, Level Etc, Parts Etc	6,865,852	19,373,286
9018	Medical, Surgical, Dental Or Vet Inst, No Elec, Parts	7,629,832	11,965,021
9031	Machines, Nesoi In Chapter 90; Profile Project, Parts	9,846,067	4,944,450
9027	Inst Etc For Physical Etc Anal Etc; Microtome; Parts	4,382,113	344,5547
9029	Revolution & Production Count, Taximeters Etc, Parts	941,662	138,0299
9013	Liquid Crystal Devices Nesoi; Lasers; Opts Appl; Parts	493,701	1,362,627
9005	Optical Telescopes & Mount; Astro Inst & Mount, Parts	132,038	810,492
9024	Machines Etc For Testing Mech Prop Of Material, Parts	401,035	771,435
9001	Optical Fibers & Bund Etc; Pol Sheets; Unmoun OParts Elem	507,944	766,090
9030	Oscilloscopes, Spectrum Analyzers Etc, Parts Etc	853,243	628,946
9021	Orthopedic Appl; Artif Body Parts; Hear Aid; Parts Etc	517,616	590,221
9022	X-Ray Etc Apparatus; Tubes, Panels, Screen Etc, Parts	804,677	467,184
9015	Survey, Hydrogr, Meteoro Etc Inst; Rangef Etc, Parts	471,955	429,288
9014	Direction Finding Compasses & Navig Inst Etc, Parts	197,328	200,508
9019	Mech-Ther, Massage, Psych Test, Ozone App Etc, Parts	220,969	179,687
9033	Parts, Nesoi For Machines, Appln, Inst/ ApParts Of Chap90	61,816	156,828
9003	Frames & Mountings For Spectacles, Goggles Etc, Parts	109,108	148,261
9011	Compound Optical Microscopes; Parts & Accessories	8,493	143,837
9002	Optical Elements, Mounted; Parts & Accessories	95,247	137,018

The significance of therapeutic appliances (eye-glasses, hearing aids, etc.) in household's total medical spending is around 30 percent in Slovakia compared to 12 percent, the average across OECD countries.

Barriers

Health care debt remains a key concern in the Slovak health system.

Medical device or pharmaceuticals importers may sometimes have problems in obtaining approval to be placed on insurance reimbursement lists—something that is also a challenge in other Central and Eastern European countries. If a product is not included on the reimbursement scheme paid by insurance companies, the market for the product is limited. Catalogue of reimbursed operations, medical aids and pharmaceuticals is reevaluated every

three months. Drug categorization takes place on monthly basis, on the first day, and impacts 200 drugs. Drug price referencing is executed twice yearly and influences almost ¼ out of 4,500 drugs.

Trade Events

Slovak Dental Days

September 1–2, 2015 • Bratislava, Slovak Republic • bit.ly/1o7IUPW

Exhibition of dental instruments, tools, and materials, supported by the Slovak Chamber of Dentists and Association of Dental Producers and Sellers. The Slovak Republic's top event for dental suppliers.

SLOVMEDICA

October 1–2, 2015 • Bratislava, Slovak Republic • bit.ly/1APC0IH

The latest medical techniques, technologies, and equipment for experts active in the field of medicine, and working in hospitals and nursing homes; as well as expert health education and science.

NON-HANDICAP

October 1–2, 2015 • Bratislava, Slovak Republic • bit.ly/1APC0IH

Annual specialized exhibition for handicapped people. Will host exhibitors promoting equipment and medical aids for the disabled.



South Africa

Market Entry

U.S. companies entering this market must contend with a typically mature and competitive market with well-established European and Asian competition. A trade agreement with the European Union enables many European products to enter South Africa duty-free or at lower rates than U.S. products.

Because the South African market is sophisticated, entry should be well-planned, taking into consideration:

- The skewed demographic income distribution pattern
- The price-sensitive nature of the majority of consumer demand;
- Increasing consumer protection enforcement albeit in a still largely non-litigious environment;
- South Africa's position as the pre-eminent stepping stone for developing most sectors in the sub-Saharan Africa: the marketing mix should anticipate this medium-term option.

A judicious selection of one of three low-risk entry strategies (representation, agency, or distributorship) is required by new-to-market entities. If you are selling to the government or to government-funded organizations, any local partner should be B-BBEE compliant and be aware of local procurement regulations.

Current Market Trends

Market growth will likely be influenced by national legislation related to the government's NHI program, as well as the Competition Commission's investigation into private healthcare costs. Government spending in healthcare has risen to approximately 9.1 percent of GDP (2014), and may increase as the government plans to overhaul primary healthcare facilities as part of their Operation Phakisa.

Statistics

Capital: Pretoria
Population: 51.7 million (2011)
GDP (USD): 350.63 billion (2013)
Currency: South African rand (ZAR)
Language: English (business), others

Contact

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National priority is given to communicable diseases such as HIV/AIDS and tuberculosis. However, there is increasing focus on chronic and lifestyle diseases such as asthma; cancer; diabetes; obesity; coronary, and vascular disease and osteoporosis. Opportunities exist for technologies that avert or reduce disability because of these diseases.

Main Competitors

Although the medical device market in South Africa continues to be dominated by the U.S., followed by Germany; Chinese suppliers made considerable inroads in 2014, with their market share reaching double digit growth. They will continue to consolidate their position as an avenue for lower cost products. U.S. and Germany's share fell in 2014, primarily because of the weakening rand against the dollar. Imports measured in USD declined due to the currency weakness and this trend is likely to continue in the short to medium term, particularly in light of the low economic growth and a tighter fiscal policy being adopted. Forecasts for this market in the long term look a little more promising, as government's pledge to allocate more resources is likely to bump up local demand.

Competition from local production will be muted, and mostly limited to consumables (bandages, dressings, etc.) and furniture. However the local development of Lodox Systems, a full-body X-ray machine indicates that local producers can successfully compete with international suppliers of sophisticated equipment if they have access to the appropriate funding channels.

The South African government published draft medical device regulations in April 2014, but it is presently unclear when these regulations will become law. The exception is electro-magnetic devices, which are regulated by the South African Health Department for Radiation Control. These products must carry the CE mark. FDA approval alone will not be sufficient.

Current Demand

Medium-term prospects for the medical device industry look promising. The market is expected to grow at a compound annual growth rate of 8.7 percent from 2012 through 2017, but it is extremely price-sensitive. The sophisticated South African medical community is generally interested in new technology developments and products. The South African government is also revamping public hospitals and building new clinics as part of their campaign to introduce and develop national health insurance (NHI), however there are considerable delays and challenges in implementation.

Registration Process

South Africa does not have a comprehensive system for medical device regulation, yet. But there will be no opportunities for products that are not FDA approved and carry the CE mark.

The South African Health Department has drafted policy documents aimed at establishing the South African Health Products Regulatory Authority which will regulate all health products—devices and pharmaceuticals. The regulatory framework is likely to lean towards European Community guidelines. Products will need to carry the CE mark in addition to FDA approval. The exception is electro-medical devices (radiation emitting devices), which are regulated by the South African Health Ministry: Directorate—Radiation Control. FDA approved only electro-medical devices are not acceptable. All electro-medical devices must carry the CE mark.

U.S. exporters must appoint a South African representative to obtain regulatory approval from the directorate and an import certificate.

Barriers

Electro-medical devices that are FDA approved only are no longer acceptable. The device must carry the CE mark.² There are national plans to reform the regulatory authority in South Africa by dismantling the Medicines Control Council and replace it with the South African Health Products Regulatory Authority (SAHPRA), which will report to the Ministry of Health. SAHPRA will regulate all health related products—including devices, which are currently not regulated (excepting electro-medical and combi-devices). Devices will need to carry the CE mark. FDA approved only devices will not be acceptable.

At present, combination devices—devices that have a pharmaceutical attached to them are regulated by the Medicines Control Council (MCC). This is a lengthy, complicated process with wait times of 48 months or more, before the product comes to market. All pharmaceuticals are also in for a lengthy wait due to the complicated and non-transparent regulation procedure with the MCC.

Trade Events

Africa Health

June 8–10, 2010 • Johannesburg, South Africa • africahealthexhibition.com

Trade Associations

- Healthcare Procurement, www.etenders.gov.za
- Government Health Plans, www.health.gov.za



Spain

Summary

Spain has a comprehensive public health system that accounts for approximately 85–90 percent of the sector's activity. The market for healthcare technology equipment in Spain is estimated at EUR 6.9 billion (USD 9.2 billion) for 2014 and is expected to increase by approximately 2 percent in 2015.

Spain is no exception to the tendency across the European Union to reduce health spending as governments grapple with budget deficits. Given the economic challenges that Spain has been facing since 2008, the level of procurement in the healthcare sector has experienced substantial cutbacks.

The sector relies heavily on imports. Despite difficult economic circumstances and budget cutbacks, imports in 2014 increased slightly to approximately USD 6.4 billion. The United States has approximately 25–30 percent of the market share, second after Germany at 50 percent.

Spanish exports, driven by the internal economic crisis and the need to develop new markets, have increased continuously over the past several years. Exports for 2014 are reported at EUR 2.2 billion (USD 2.9 billion) in 2014, an increase of 6 percent over the previous year and 13 percent total increase since 2008. The European Union (EU) accounts for almost 70 percent of these exports, while exports to Asia have increased by 30 percent.

Large companies account for only about 8 percent of the market but they generate approximately 60 percent of the turnover. Most of the large U.S. names are well established in Spain and often represent serious competition for companies trying to break into the market.

Statistics

Capital: Madrid
Population: 47.7 million
GDP (USD): 1.4 trillion
Currency: Euro (EUR/€)
Language: Spanish

Contact

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Market Entry

All medical products/equipment imported into Spain need to have the CE Mark. Because of this requirement, many U.S. companies have been centralizing their import operations into one single country where they register the products and from which they distribute their products to the rest of the EU.

Most purchases (85–90 percent) are made through public hospital tenders from companies that are pre-selected for public tender opening bids. That is the main reason why having a qualified importer/ distributor with access to the procurement decision makers is so important for U.S. companies. In addition, all importers/distributors of medical equipment and products into Spain need to be resident in the EU and registered with the Spanish Ministry of Health.

The import of refurbished medical equipment into Spain is technically permitted, but both public and private medical providers in Spain have traditionally preferred new equipment. Refurbished equipment also requires a current CE mark.

The official approach to vitamins and health supplements in Spain is quite different to that of the United States. Many vitamins and supplements commonly found in the U.S. health food stores are still considered by the Spanish Ministry of Health as prescription medicine and are approved as such. U.S. companies interested in the Spanish market need to provide the Spanish Ministry of Health with technical data on the product's composition and need to meet the labeling requirements. The approval of products considered drugs can be lengthy.

U.S. products that are competitive in price or innovative in the U.S. market and that are already being sold in European markets have a better chance of success in Spain.


Current Market Trends

U.S. medical equipment is highly regarded by Spanish doctors, domestic importers, and distributors. However, current budgetary concerns and the ongoing need to reduce public spending are severely limiting current procurement and growth.

Based on OECD statistics, Spanish healthcare spending is in the range of 9 percent of GDP, in comparison with 10.5 percent in Belgium, 11.1 percent in Denmark, 11.6 percent in France, 11.3 percent in Germany, 9.2 percent in Italy and 9.4 percent in the U.K.

FENIN, the Spanish Healthcare Technology Federation, estimates that despite a two percent increase in the national healthcare budget for 2015, as of the end of 2014 the level of activity in the sector had experienced a setback of 17 percent during the period of 2010–14.

The last few years have seen a significant shift in sourcing. In an effort to restrain/reduce expenditures, more and more items are being imported from Asia. However, when it comes to more complex and sophisticated items, quality continues to be an important factor in the purchasing decision.



Prior to the current crisis, diagnostics, orthopedics and disposable items had accounted for 70 percent of the market. Once the market recovers, best products would include innovative and efficient cardiology, respiratory/anesthesia, neurology, orthopedic, MRA, ETP, CT, and dermatology/wound treatment products.

The drop in demand, exacerbated by reimbursement delays and lack of financing, has caused serious cash flow problems for numerous distributors/importers, particularly the smaller ones that make up the bulk of the distributors. These companies rely on the most part on their dealings with the Administration to cover most of their operating expenses and actively participate in public tenders. Many companies have closed over the last several years while many others have opted for an extremely conservative approach. Contrary to their traditional way of operating, numerous companies currently prefer to focus their efforts on essential basic products rather than on new products, as they are wary of making up-front investments without any guarantee of generating demand.

According as the economic situation improves, opportunities will arise in areas that are changing. Due to improving life expectancy, a growing ageing population will generate greater demand for products directly connected with geriatric ailments and illnesses.

Likewise, EU emphasis on E-health will continue. Sector experts agree that healthcare technology is a key component to the growth of the market. The healthcare technology sector invests 9.5 percent of its turnover in Research and development. However, as the roll-out of this sector relies on public funding and is implemented on a regional rather than a national basis, progress in this sector will continue to be slow and the level and rate of deployment will vary throughout the country.

Main Competitors

The United States and Germany are the two main suppliers, with France, the U.K., Italy and Switzerland following. However, France, the U.K. and Holland are also used as storage and redistribution centers for U.S. companies. Imports from Asia are on the rise.

Many suppliers in the Spanish industry are subsidiaries of overseas corporations, including leading U.S. companies. These well-established companies often represent serious competition for companies trying to break into the market.

Current Demand

According to FENIN, the sectors that showed a slight increase include ophthalmology (5 percent), dental (6.9 percent), information systems and clinical technology (14 percent), orthopedic implants, surgery, and nephrology. In contrast, electro medical devices continue to decrease due to the reduction in acquisition and/or renewal of new equipment in the hospitals; other areas that experienced negative growth include: cardiology (negative 8

percent); disposables (negative 7 percent) and home care oxygen therapy and medicinal gases (negative 3 percent).

Trade Events

There are no major trade shows specifically for medical devices. Congresses and conventions, however, often include an exhibition area. Several international events are scheduled to take place in 2015–16.

ECAMS 2015 (International Congress of the European College of Aesthetic Medicine and Surgery)

October 2–3, 2015 • Barcelona, Spain • congress.ecamedicine.com

CPhI Worldwide Madrid

October 13–15, 2015 • Madrid, Spain • cphi.com/en/europe/home

UEG Week 2015 (United European Gastroenterology)

October 24–28, 2015 • Barcelona, Spain • www.ueg.eu/week

World Vaccine Congress

November 9–11, 2015 • Madrid, Spain • 10times.com/world-vaccine-congress-madrid

INFARMA

March 8–10, 2016 • Madrid, Spain • ifema.es

ORTO Medical Care

November 24–26, 2016 • Madrid, Spain • 10times.com/orto-medical-care

Sweden

Summary

Sweden's health care system is one of the best and most well developed in the world. The population of 9.7 million enjoys very good health. Sweden invests about 11 per cent of its GDP in health and medical services, which is on par with most other European countries. The infant mortality rate is less than 2.7 deaths per 1,000 in the first year of life and the average life expectancy is 80 years for men and 84 years for women. As Sweden has a population that is one of the oldest in the world, 19.4 percent are 65 years or older, there will be an increasing demand for medical equipment and supplies, and longer medical treatments, to meet the health needs of an ageing population.

The responsibility for health and medical care in Sweden is shared by the central government, the county councils and the municipalities. Sweden is divided into 290 municipalities and 21 county councils. The county councils have the responsibility to provide health and medical services and to work for a good standard of health among the population. They also decide on the allocation of the resources to the health services and are responsible for the overall planning of the services offered. It is also the county councils that own and run the hospitals, health centers and other institutions. County Councils are also responsible for dental care for local residents up to the age of 20. The 290 municipalities are responsible for the nursing homes, care of the elderly in their homes and the disabled. They are also responsible for providing care for people with psychological disorders and providing support and services for people released from hospital care as well as for school health care. Private health care, accounting for some twelve percent of total health care costs, mainly offers primary care like running health care centers or homes for the elderly. There are a few hospitals that are managed by private entrepreneurs.

Statistics

Capital: Stockholm
Population: 9.7 million
GDP (USD): 570.6 billion
Currency: Swedish krona (SEK)
Language: Swedish

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There are some 90 hospitals in Sweden of which 60 provide specialist care, with emergency services. Seven of these are regional hospitals offering highly specialized care and where teaching and research is based. There are about 35,000 physicians and 110,000 nurses in Sweden. Outpatient care is organized into primary care districts, each with 5,000 to 50,000 inhabitants.

According to trade sources, the Swedish market for medical equipment was estimated at USD 2.8 billion in 2014. For the next coming years, the market is expected to show a moderate growth, around 4 percent per year. Domestic production is strong (in areas such as wheelchairs, hospital furniture, sterilizers, blood pressure monitors) and Swedish innovations such as the pacemaker, hemodialysis and the gamma knife have gained international recognition. As most of the domestic manufacture is for export (estimated value at USD 2.9 billion), the medical equipment market is dependent on imports. In 2014, imports were estimated at USD 2.5 billion.

Market Entry

Business Monitor ranks Sweden as the eighth most attractive market in Western Europe in which to commercialize a medical device. To successfully enter the Swedish market, U.S. companies are recommended to establish a local presence, either through local agents, distributors or sales subsidiaries. All products sold in Sweden must carry the CE mark. In addition, all labeling and instruction manuals must be translated into Swedish.

Sweden's customs laws and regulations follow those of the EU. This means that Sweden applies external EU tariffs to imports from the U.S. and other non-EU countries. Goods imported to Sweden are also subject to a value-added-tax (VAT) of 25 percent. Sweden uses the metric system and products sold in Sweden should be adapted for use with the metric system whenever possible. Electric current in Sweden is 50 Hz, AC 230V single-phase and 230/240V three-phase.

Current Market Trends

Two main factors are expected to strongly affect Sweden's the future health care system:

- An aging population, which is likely to lead to increased demand for health care products as well as health care related services such as equipment and supplies for the home health care sector.
- Lifestyle related diseases (diabetes, obesity, etc.).

Of the predominant diseases the main causes of death are cancer and cardiovascular conditions including strokes. Chronic diseases that require monitoring and treatment, and often life-long medication, place significant demands on the system.

The incidence of smoking, however, has been falling in Sweden since the mid-1980s. According to a study by the European Union, Sweden has the lowest proportion of smokers (18 per cent) among EU member states.

Main Competitors

Domestic production is strong (wheelchairs, hospital furniture, sterilizers and blood pressure monitors) and the medical device sector is one of the leading export sectors in Sweden. Some of the internationally known Swedish medtech companies include Getinge (Medical Systems, Extended Care and Infection Control), Molnlycke Healthcare (single-use surgical and wound care), and Elekta (the Leksell Gamma Knife). Major global companies with a strong presence in Sweden include GE Healthcare, Baxter, Fresenius, Philips, Abbott, Thermo Fisher, Johnson & Johnson, Siemens, and Nobel Biocare.

Current Demand

The Swedish health care market is advanced and there is an eagerness to be at the forefront of technological developments. The market looks to the U.S. for developments in research and application of the newest medical technology. U.S. companies will find that the market is quite receptive to high-quality equipment that offers both ease of use and cost efficiency. Future demand is expected in the following areas:

E-health, Telemedicine, mHealth, Non-invasive surgical equipment, Orthopedic and prosthetic equipment and Home health care and Assistive Technologies equipment and supplies.

Registration Process

The Medical Products Agency (MPA, lakemedelsverket.se) is the Swedish national authority responsible for regulation and surveillance of the development, manufacturing and marketing of medical devices, drugs and other medicinal products.

Barriers

There are no significant trade barriers to U.S. medical devices.

Trade Events

Apoteksmassan

September 2015; September 2016 • Stockholm, Sweden • apotekegenvard.se

Pharmacy and over-the-counter products.

SweDental

November 2015 • Goteborg, Sweden • bit.ly/1ONbNKj

Dental conference and trade show.

Health, Wellness & Fitness

November 2015; November 2016 • Stockholm, Sweden • alltforhalsan.se

Vitalis

April 2016 • Goteborg, Sweden • vitalis.nu/en

Telemedicine and e-health.

Resources

- Healthcare Procurement, opic.com
- Government Health Plans—Ministry of Health and Social Affairs, bit.ly/1SLDy6a



Taiwan

Summary

With a population of 23 million, Taiwan is a thriving democracy, vibrant market economy, and a highly attractive export market, especially for U.S. companies. In 2014, Taiwan was ranked as the United States' 10th-largest trading partner in goods, placing it ahead of markets such as India and Italy.

In 1995, Taiwan launched the National Health Insurance (NHI) program, and has provided universal health coverage (99.9 percent of the population) through a single payer system ever since.

There are over 20,000 primary and 500 secondary care units in Taiwan, many of which are small, privately owned clinics. In 2014, roughly 93 percent of all health care facilities were contracted by the NHI system to provide healthcare service. Beginning in 2013, Taiwan's NHI entered its second generation phase, which focuses on applying internet, cloud and other information technologies to the system to optimize use and efficiency. Many of the more advanced medical devices are too expensive for the NHI system to reimburse their users. In this case, a self-pay category is utilized.

Due to limited market size, Taiwan manufacturers export the majority of their products to foreign markets, which consists of primarily low to mid end medical equipment and contracted manufacturing for multinationals. The opportunity for imports is at the high-end where the United States and Japan have been the primary partners. Over 70 percent of the market is still supplied by imports, of which the U.S. holds one third, or approximately 34.9 percent, of the market share.

Market Entry

It is essential to appoint a local distributor for any manufacture wishing to enter Taiwan. Private hospitals in Taiwan tend to deal on a one-to-one basis with local agents. Equipment tenders for public hospitals are handled through the

Statistics

Capital: Taipei

Population: 23.3 million

GDP (USD): 529.6 billion

Currency: New Taiwan dollar (TWD)

Language: Mandarin

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government procurement agency. According to the Taiwan Ministry of Health and Welfare, there are 55,926 registered dealers of medical devices and pharmaceuticals.

Current Market Trends

Twelve percent of Taiwan's population in 2014 was over the age of 65. This, some say, is in part due to a successful health care system. In 2013, Taiwan's health expenditure was 6.6 percent of gross domestic product (GDP) and is expected to grow annually at a rate of 4.7 percent putting further strain on healthcare expenditures in the coming years. This trend however, is not merely driven by an aging population, but economic performance, a universal healthcare coverage system and an increasing prevalence of chronic disease also contribute. About 62 percent of Taiwan's healthcare expenditures are funded by the public sector with the remaining 38 percent covered by out-of-pocket private spending. Taiwan also had one of the highest per capita healthcare spending trends in the Asia Pacific region in 2014, at USD 2,546 per person, one third of the United States.

Main Competitors

The medical manufacturing sector in Taiwan mostly consists of small to medium sized enterprises. The sector is particularly strong in manufacturing products in the lower end of the technology scale. Taiwan is one of the world's leading producers of wheelchairs, patient aids, rehabilitation products, bandages and other medical supplies, and basic medical/surgical instruments. The local sector has also gradually expanded into orthopedic and implantable products, contact lenses and other medical instruments and devices such as blood pressure and glucose monitors.

For pharmaceutical industry, Taiwan has approximately 1,900 manufacturers of Western-style medicines and about 200 Chinese medicine producers. The Taiwan drug market is heavily reliant on imported drugs. Most major international pharmaceutical companies are widely represented on the island.

Current Demand

High import demand over high-tech end market: Approximately 70 percent of the medical device market is supplied by imports especially at the high-tech end of the market. The imported advanced medical devices are generally from the United States, EU and Japan, with the trend remaining strong.

Registration Process

According to the regulations set by the Ministry of Health and Welfare (MOHW), companies that import to Taiwan must submit the required documentation through their Taiwan importers or subsidiaries. Medical devices must apply for reimbursement review while

pharmaceuticals must be approved by the Taiwan Food and Drug Administration (TFDA) before entering the market.

Barriers

According to the USTR “2015 National Trade Estimate Report,” in the pharmaceuticals industry, stakeholders continue to underscore the need to create a more predictable market for pharmaceuticals, including innovative pharmaceuticals, in Taiwan’s health care system. Concerns include whether Taiwan health authorities will take steps to provide greater consistency in the treatment of patented pharmaceutical products, how to calculate annual drug expenditure targets, and how to clarify what actions will be taken if targets are exceeded. For Medical Devices industry on the other hand, USTR expressed concerns over Taiwan’s product license approvals and pricing review mechanisms.

Trade Events

Taiwan International Medical & Healthcare Exhibition

June 2016 • Taipei, Taiwan

Geriatric/Elder Care Asia

November 2016 • Kaohsiung, Taiwan

Resources

- Healthcare Procurement, bit.ly/1LQvTTO
- Government Health Plans, www.nhi.gov.tw/english

Tanzania

Summary

Healthcare in Tanzania is available, but dependent on one's affluence and accessibility. For the most part, people residing in urban areas have more access to private and public health facilities than those living in rural areas. Demand for high quality and affordable care for all citizens is growing, and the government of Tanzania has, since early 2013, been in the process of developing a health financing strategy. Data is limited, but there has been a sizeable increase in the health budget from USD 743 million in 2002/2003 to USD 1.75 billion in 2009/2010 according to National Health Accounts. Donors have remained the main financiers. Health insurance coverage is very low, which translates to an over-reliance on direct payment at point-of-care. This in turn denies the poorest people from accessing much needed healthcare.

Tanzania's burden of disease is high. Approximately 5.2 percent of the adult population suffer from HIV/AIDS (2012 estimates) and the country is a high risk area for additional infectious diseases such as Malaria (leading cause of death in children and maternal mortality); bacterial diarrhea, Hepatitis A, Typhoid Fever, Dengue Fever, Rabies, Rift Valley Fever, Schistosomiasis, Leptospirosis and more. Five percent of the adult population suffers from obesity; conversely around 16 percent of children are underweight and suffer from malnutrition. Tanzania has a maternal mortality ratio of 460 deaths per 100 000 (2010 estimates), with infant mortality rates of 43.74 deaths per 1000 live births (2010 estimates).

Market Entry

The most effective way of moving goods and services from U.S. producers to industrial and consumer users is through an agent or distributor. Typically agents or distributors will enter into a Distributor's Agreement with U.S. producers to

Statistics

Capital: Dodoma
Population: 49.6 million (2013)
GDP (USD): 86 billion (2014)
Currency: Tanzanian shilling (TZS)
Language: English (business),
Swahili (official), others

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operate as wholesalers to sell goods and services to local organizations or companies. Some distributors also operate as retailers and sell directly to final consumers.

Use of an agent or distributor has three advantages:

- Enables companies to maintain continuity
- Places the task of ensuring payment on the local partner and, as such, reduces risk and costs
- Provides protection to U.S. suppliers inexperienced in Tanzanian business practices

In general, finding a reliable agent or distributor requires a visit to meet with local businesspeople. The U.S. Commercial Service in Dar es Salaam can assist U.S. companies interested in a relationship with local partners.

Current Market Trends

Tanzania is a low-income country, with poor infrastructure and spotty access to healthcare. Purchasing of devices and pharmaceuticals is dependent on available funding. Procurement in the public sector is usually done via tender. The overwhelming majority of health devices and medicines will be imported, often from Kenya and South Africa.

Registration Process

You must obtain market authorization from the Tanzanian Food and Drugs Authority (TFDA) to commercialize your device in Tanzania. TFDA regulations are based on Global Harmonization Task Force (GHTF) recommendations, and require all device manufacturers to have certificates of registration prior to market entry.

Barriers

Trade reforms have abolished import and export licenses, except for goods deemed sensitive for health and security reasons. Trade regulations and standards generally reflect normal expectations to protect consumers' health.

The customs department and the port authorities are the greatest hindrance to importers throughout Tanzania. Clearance delays and extra-legal levies are commonplace when dealing with customs officials within the Tanzania Revenue Authority (TRA). These hindrances can cause unpredictable delays when importing goods into the country.

However there are some benefits for large taxpayers who have a track record of compliance, including expedited clearance and reduced auditing.

Resources

- Tanzania Food and Health Authority (TFDA), tfda.or.tz



Thailand

Market Entry

For U.S. manufacturers wishing to gain market entry, it is highly recommended they work with local agents/distributors. Local agents provide immediate access to an established marketing network and in-depth knowledge of regulations. A critical role of local representatives is to provide after-sales service support to customers and to develop and maintain strong personal relationships with customers. In Asia, relationships play a key role in business and greatly influence customers' procurement decisions. An agent's role includes all marketing of the products and as well as handling all product registration with Thailand Food and Drug Administration (FDA), a requirement prior to any importation.

Current Market Trends

Medical tourism in Thailand accounts for 10 percent of the Thai economy. It is also considered a top destination in Southeast Asia as a low cost healthcare venue. On average, Thailand receives 1.4 million medical tourists a year. In 2013, Thailand earned USD 4.31 billion in revenue from medical tourism, after average growth of 15 percent a year over the past decade. Hospitals in Bangkok serve more than 43 percent of medical tourists coming to Asia. In line with the growth, foreign investment in Thailand's health sector is also increasing. Recently, there have been mergers and acquisitions of private hospitals, aiming for broader customer base and increased access to potential markets.

As a result, the medical device industry is thriving in Thailand. Thailand has over 1,000 public hospitals and 400 private hospitals. Thailand relies on imports for higher value and more sophisticated medical devices. Approximately two-thirds of the medical devices in Thailand are imported. In 2014, Thailand's imports of medical device were valued at USD 1.35 billion; imports from the United States accounted for 30 percent. Generally, Thai manufacturers produce lower-end medical devices, which are more labor intensive, these include disposable syringes,

Statistics

Capital: Bangkok
Population: 68.5 million
GDP (USD): 387.25 billion
Currency: Thai Baht (THB)
Language: Thai

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disposable test kits, and surgical latex gloves. Public hospitals in Thailand make up roughly 55 percent of the total medical device purchases. Market growth, however, is fueled mostly by medical facility upgrades and replacements largely at specialized private hospitals.

Thailand's vitamin and dietary supplements market has high potential due to strong demand, but is highly competitive with abundant local and foreign brands already dominating the marketplace. Thais are among the top consumers of vitamins and dietary supplements in the world. In 2013, the sales value of dietary supplements in Thailand was estimated at USD 833 million, with a projected annual growth rate of 10–15 percent over the next five years, reaching USD 1.7 billion in 2018.

Main Competitors

U.S.-made products have the lead in the higher-end medical device market, clinical diagnostic laboratory equipment market and biotechnology segments. They face strong competition, however, from European and Japan companies.

Current Demand

Medical devices with the best growth opportunities include surgical procedure equipment, diagnosis equipment and devices for lung and heart diseases treatment. Examples include respiratory devices, orthopedic implant devices, heart valves and neurosurgical devices. The dermatological device market also has good potential, as standalone skin care and dermatological clinics have become very popular in the recent years. Some of Thailand's beauty clinic chains have also expanded to neighboring countries like Cambodia, Laos, Myanmar, and Vietnam. Best prospects for dietary supplement products include antioxidant and anti-aging supplements, blood circulation supplements, brain supplements for kids, and supplements for sport applications.

Registration Process

Importing medical device, pharmaceuticals, food supplements, products for animal health, or other medical substances into Thailand requires registration with the Food and Drug Administration of Thailand (FDA). The time required for filing a product registration application in Thailand and receiving registration certificates with the FDA can vary widely.

Drug Registration

All pharmaceutical products, including chemical, biological, and combination products, are regulated by the FDA in accordance with the Drug Act. Before launching any pharmaceutical products in Thailand, companies must first obtain a license from the FDA to produce, sell, or import the products into the country. The registration process can take approximately two years. In addition, companies must also obtain marketing approval, which means registering their product for actual sales.

According to the Drug Act, a certificate of product registration is valid for five years from the date of issuance. The process of drug registration will be carried out in two channels, which differ in degrees of control and dossier submission: registration of general medicines vs. registration of Thai traditional medicines

Due to some differences in the requirements for dossiers to be submitted for product approvals, the general medicines will have to be further defined as:

- Generics whose registrations require only dossiers on product manufacturing and quality control along with product information;
- New medicines whose registrations require a complete set of product dossiers;
- New generics whose registrations require dossiers of bioequivalent studies in addition to the required dossiers for generics submission.

“Generics” include pharmaceutical products possessing the same active ingredients and dosage forms as those of the original products, but manufactured by different manufacturers. New medicines include products of new chemicals, new indications, new combinations or new delivery systems and new dosage forms. New generics are medicines with the same active ingredients, doses and dosage forms as those of the new compounds registered after 1992.

For more information, visit www.fda.moph.go.th/eng/drug/index.stm.

Food Supplement Registration

Prior to starting the registration process for a food product, the Thai FDA must first approve all ingredients of the products. An ingredient that is commonly registered in another country may not necessarily have been registered with the Thai FDA. For new ingredients, the FDA will request additional supporting documents. For example, a product used in food consumption must be able to show a history of use for more than 15 years in a foreign country and/or safety data. Companies need to make strategic decisions about whether to retain the new food ingredient in a formula. On the one hand, the new ingredient can be helpful in differentiating the product from competitors, but on the other hand companies face an extended registration process when new ingredients are included.

Prior to FDA submission, an applicant must provide (1) the ingredient list for its products; (2) the source of the ingredients; (3) the manufacturing process; (4) the objectives of use; and (5) the targeted consumer group.

To register with Thai FDA, following documents and information are required:

- Two samples of each product
- A production flowchart
- Details of the exact composition by percentage of each ingredient
- Six labels

Products must display the following information for consumers:

- Name and brand of the product (both generic and trade)
- Registration number
- Name and address of the manufacturer
- Name and address of the importer
- Manufacturing and expiry dates
- Net weight and volume
- Any additives used
- Health and nutritional claims

A health supplement is classified as a food supplement if it contains common herbal ingredients and other bioactive ingredients at a daily dosage level recognized by the Thai FDA as safe for food. For common vitamin and mineral supplements, the levels of the nutrients must be kept between 15–100 percent of the Thai Recommended Daily Intake (RDI) in order to be classified as a food supplement.

In terms of bearing nutritional claims, such as nutrient content or comparative nutrient claims, health supplements regulated as food supplements are permitted to bear claims that are in line with the Codex Alimentarius nutrition labelling guidelines. For claims pertaining to functions of nutrients (e.g. vitamin A for night vision, Calcium for healthy bones), food supplement products are permitted to bear claims that are in the Thai FDA's permitted list of nutrient function claims for conventional food.

It is important to note that as a member of the Association of South East Asian Nations (ASEAN) working group on the harmonization of health supplements and traditional medicine, the Thai FDA is in the process of reviewing its regulatory framework for evaluating the substantiation of health claims. Food supplements are not permitted to bear medicinal claims, unless the product is registered as a traditional medicine or drug.

Health supplements containing ingredients not approved as food ingredients and/or containing vitamins and minerals that exceed the Thai RDI value, must be registered as traditional medicines, drugs or any other related sub-categories, such as modern herbal drugs, generic drugs or new drugs. Glucosamine, for example, is considered a generic drug, whereas echinacea is considered a traditional medicine. Products classified as food supplements require a notification process.

In general, it takes approximately six months to register food/food supplement products with Thai FDA. Food import licenses must be renewed every three years. For more information, visit www.fda.moph.go.th/eng/food/index.stm.

Medical Devices Registration

The current Thai medical device regulatory regime has been in place since 2008 and requires foreign device companies to register their medical devices. Under the Thai FDA, the Medical Device Control Division (MDCD) oversees medical device regulation enforcement. The device classification framework in Thailand is based on a risk system that is the completely opposite

to most other classification systems—devices are categorized as Class III (low risk) through Class I (high risk).

The Thai FDA groups medical devices into three subcategories

- **Class 1: Licensed Medical Devices**—This is the most rigorously controlled class, comprised mainly of condoms, HIV diagnostic kits, contact lenses, and so on. Several details must be submitted to the FDA, including certificate of free sale, certificate of quality system of manufacture (for example, the relevant ISO certificates), clinical evaluation, sterility, stability, raw material and finished product specifications, Thai label and leaflet, product photo, and manufacturing process.
- **Class 2: Notification Medical Devices**—The level of control in this class is less stringent than class 1. Examples of medical devices in this class include physical therapy products, silicone breast implants, and alcohol detectors. The documents required for submission to the FDA are similar to those of class 1. An applicant must prepare the dossier according to the CSDT.
- **Class 3: General Medical Devices**—This class is subject to the least stringent control by the FDA. All medical devices which are not classified as class 1 or class 2 fall in this class. The required documents include certificate of free sales from the country of product owner, catalogue/product photo, Specifications, and ISO 13485 (in some human use product categories, for example implant products and sterile products).

For more information, visit www.fda.moph.go.th/eng/medical/index.stm.

Certification and Legalization

Foreign medical device companies wishing to sell their products in Thailand must first register them according to a risk-based classification system. The authenticity of Certificates to Foreign Government must be further attested to by U.S. Commercial Service in Bangkok.

The U.S. Commercial Service can facilitate the certification and legalization of documents as required by Thai FDA. The standard timeframe for completing a certification service is three business days from the date of documents submission.

Barriers

Thailand has rigorous regulatory requirements and lengthy product registration. U.S. companies have also faced increased competition from cheaper healthcare products from other countries.

Trade Events

Medical Fair Thailand 2015

September 10–12, 2015 • Bangkok, Thailand • www.medicalfair-thailand.com/index.php/en

Turkey

Summary

Turkey has a population of 81 million people and is a growing market for medical technologies and healthcare services. The Ministry of Health (MOH) is the largest provider of healthcare and the only public provider of preventive services in Turkey. At a national level, MOH is responsible for the country's health policy and health services. In fiscal year (FY) 2014, TL 18.6 Billion (approximately USD 9 billion) was allocated to the Ministry's budget, which is an increase of 10 percent in TL terms compared to FY 2013. Turkish medical equipment market is approximately USD 3 billion and has been growing at the rate of 5–10 percent every year since 2002. 90 percent of the products used are imported; however, there is strong push by Turkish government to strengthen and grow local manufacturing. In the coming years, percentage of imported products in the market may go down; however, Turkey and region will continue to be an attractive market for advanced and innovative U.S. products.

Market Entry

U.S. medical equipment manufacturers can either open their own offices in Turkey and equip it with their own sales and marketing force or appoint national and, most of the time, exclusive distributors in Turkey. The distributor/importer should have strong reseller base to market and service the products all around the country, follow the tenders and also be knowledgeable about importing medical devices into Turkey.

Current Market Trends

Turkey has a 2-level approach to the delivery of public healthcare services. First-level treatment is delivered by family practitioners who are appointed to population groups of 3,000 people living in the same area. For illnesses requiring further treatment, patients are referred by family practitioners to second-level

Statistics

Capital: Ankara
Population: 81,619,392 (est. 2013)
GDP (USD): 799.5 Billion (2014)
Currency: Turkish Lira (TRY)
Language: Turkish

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treatment facilities, which are “state” and “university” hospitals. There are 1,453 hospitals and 194,000 hospital beds in Turkey. 840 of these hospitals are built and operated by the MoH and are known as “state hospitals.” These hospitals constitute 57 percent of the current hospital stock and 62 percent of current hospital bed capacity in Turkey. There are 503 “private hospitals” and 65 “university hospitals”.

There is an emerging group of hospitals that will be built and managed by the Public-Private-Partnership (PPP) model. The MoH has recently been contracting out the construction and management of 29 healthcare campuses around Turkey. Each campus will house 500 to 3,000 beds divided among general and specialized hospitals, laboratories, and accompanying recreational areas. For more information on these projects, please visit bit.ly/186eXEt.

All people living in Turkey can benefit from being treated in these hospitals. If they are “universal healthcare insurance” holders, all of their expenses are reimbursed by the Social Security Institute (SGK, www.sgk.gov.tr). Today, 95 percent of the population is covered under this insurance plan. SGK reimburses expenses incurred by using the treatment type and medical device listed in the Healthcare Implementation Communiqué (SUT). The SUT is revised every few years to include new medical technologies, equipment, techniques, and an updated reimbursement price list. In order for medical equipment to be listed in SUT, it has to be registered in the National Databank managed by the MoH.

Turkey has been leading a rather aggressive approach since 2005 towards establishing an electronic system to manage patients’ records, reimburse healthcare expenses, manage prescriptions flow, and use of tele-medicine for offering healthcare services to remote parts of the country. The Ministry of Health’s E-Health Department cooperates with industry to develop various software to reach a position where all elements of Turkish healthcare system will be integrated in the central system. At this point, the area where there is good potential for healthIT companies is in the area of business analytics through which patient data collected in hospitals can be analyzed by management to derive decisions.

Medical tourism is a new sector developing in Turkey, which is a triggering factor in the investments made by the private sector in healthcare. Increasingly, patients from Europe and the Middle East go to Turkey for medical treatment, as costs are more affordable. Increased emphasis on medical tourism will also have a positive impact on U.S. manufacturers as it will bring create avenues for medical equipment exports.

Best prospective areas for medical device and healthIT companies in Turkey are as follows: Advanced pre-screening and diagnostics devices, advanced point-of-care devices, advanced surgical devices, cancer treatment devices, wound management devices, surgical devices using robotics technologies, dental equipment, implants used in orthopedics and traumatology, HealthIT solutions especially for clinical decision systems, remote patient monitoring devices, telemedicine systems

Main Competitors

Imports of U.S. origin is about 12 percent of the total imports market in Turkey. The rest are mainly from the European Union, predominantly from Germany, Italy, United Kingdom, France and the Netherlands, and China and India. There is also an emerging group of medical device and equipment manufacturers in Turkey, which are active in the manufacturing of disposables, orthopedic devices and tools, surgical and cardiological tools; like stents. There are close to 100 healthIT software development companies.

Current Demand

(USD Millions)	2013	2014	2015 (proj.)	2016 (proj.)
Total Market Size	2,437	2,681	2,949	3,292
Total Local Production	550	605	666	799
Total Exports	307	338	371	427
Total Imports	2,194	2,413	2,655	2,920
Imports from the U.S.	296	326	358	394

Source: Industry feedback, Turkish Ministry of Industry reports

Registration Process

Turkish medical device directives have been aligned to those applicable in the European Union (EU):

- Medical Device Regulation(93/42/EEC)
- Active Implantable Medical Device Regulation (90/385/EEC)
- In Vitro Medical Diagnosis Devices Regulation (98/79/EC)

Per the directives listed above, medical devices have to have CE Mark in order to be registered and marketed in Turkey. They should have Declaration of Conformity and EC certification given by a Notified Body authorized by the EU.

Medical devices that will be sold in Turkey have to be registered in the Turkish Medicines and Medical that is operated by Turkish Drugs and Medical Device Agency under the Ministry of Health. If the manufacturer has a subsidiary in Turkey, medical devices, in question, can be registered under this entity's name. If they are represented by a distributor in the country, this distribution company has to file in the registration under its own name.

Barriers

Turkey has Customs Union Agreement with the EU which provides that products exported from an EU country are not levied any imports tax when passing through Turkish customs.

Countries that have Free Trade Agreement with Turkey also benefit from the same application. Products exported from countries not falling into either of these groups are levied imports tax at varying amounts. This is not a trade barrier but an extra factor that U.S. companies have to take into consideration when they are establishing their pricing strategies in Turkey. Turkey also sometimes pursues protectionist approaches in favor of some of its local industries (lately for furniture industry which has had negative impact on hospital beds imported to Turkey) which results in sudden increases in the tax rates it charges on related imported products.

Trade Events

EXPOMED Eurasia

March 24–27, 2016 • Istanbul, Turkey • expomedistanbul.com/en

Resources

- Ministry of Health, disab.saglik.gov.tr/index.php
- Turkish Drugs and Medical Devices Agency, www.titck.gov.tr

Ukraine

Summary

The majority of healthcare funding in Ukraine is provided by national and local tax revenues, which have fallen short over the last several years. Ambulatory and hospital healthcare services are provided predominately by the public sector. In 2014, total healthcare expenditures were estimated at USD 9.5 billion, or USD 211 per capita, which was equal to 9.8 percent of GDP. Comparatively speaking, per capita spending on healthcare in Ukraine is the lowest in Central and Eastern Europe. Private expenditure, consisting of out-of-pocket payments, represents around half of total healthcare expenditures.

Ukraine has one of the highest numbers of hospitals and hospital bed rates in the world. This is due to Ukraine's Soviet legacy of healthcare provision that focuses on secondary care to the detriment of basic primary care. Ukraine's physician rate is in the global top ten, standing at 4.8 per thousand of population in 2014.

There is an emerging political consensus regarding the need for fundamental healthcare reform, which includes introducing a reimbursement and insurance-based healthcare system, re-allocating resources in favor of primary healthcare, and resolving the imbalance between hospital and specialized care. These reforms will boost healthcare expenditures in the long term and provide significant growth opportunities for U.S. exporters.

Major steps were taken towards healthcare reform in March 2015 when the World Bank approved a USD 214.73 million loan for the "Serving People, Improving Health" Project to support the implementation of reforms and improved service delivery in Ukraine's health sector. This new five-year project will develop medical infrastructure and improve the quality of health services in eight regions across the country.

According to Espicom Business Intelligence, in 2014, the Ukrainian medical device market was estimated at USD 523.4 million, or USD 11.7 per capita, a 30.3 percent

Statistics

Capital: Kyiv
Population: 42.8 million
GDP (USD): 383 billion (proj. 2015)
Currency: Ukrainian Hryvnya (UAH)
Language: Ukrainian, Russian

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drop from 2013. Around 90 percent of the medical device market is supplied by imports. In 2013, Ukraine imported medical devices valued at USD 665.2 million, a decrease of 15.2 percent compared with 2012. In 2014, imports decreased by 37.2 percent to USD 417.7 million.

The Ukrainian market is open to advanced medical equipment, offering ease of use and cost savings. Receptivity to used medical equipment is average. On one hand, there is a demand from end-users, but on the other hand, used equipment cannot be purchased through government tenders. However, private hospitals and clinics are in the market for used medical equipment.

Market Entry

U.S. companies entering the Ukrainian market should approach with a long-term perspective. Business in Ukraine is often based on relationships, so selecting a good local partner and/or establishing a local office are crucial to minimizing risk and long-term success. To find a potential partner, we recommend using the U.S. Commercial Service's International Partner Search and/or Gold Key programs to conduct initial screening for prospective partners. U.S. companies should use appropriate due diligence in selection of partners and should be mindful of the parameters of the Foreign Corrupt Practices Act.

Kyiv is not the only trade hub in Ukraine. Look for distributors that have nationwide capabilities, including those located in the cities of Dnipropetrovsk, Lviv, Odessa, Zaporizhzhya, and Kharkiv. These regions are considered important industrial centers in Ukraine and are densely populated. Covering the Ukrainian market from regional offices in Poland or Russia is not an effective approach. Ukrainian buyers are reluctant to go through regional offices, preferring to order direct for the manufacturer/wholesaler. On-the-ground presence is very important to successful business development in Ukraine.

Joining the American Chamber of Commerce and obtaining experienced legal and accounting support are other important considerations when considering doing business in Ukraine.

Current Market Trends

A key issue for Ukraine is to select a more efficient healthcare financing model. Today, the healthcare system is financed through general taxes and is based on contractual state purchases of healthcare services. There have been suggestions to introduce compulsory medical insurance which would attract funds to medicine from private insurance sector, though still there is no consensus in the government and the parliament as to the future model of healthcare insurance—private, state or mixed.

The Ukrainian market is receptive to high-quality, advanced diagnostic and therapeutic equipment, including surgical navigation systems, implantable cardiac devices, neurostimulation systems, diagnostic point-of-care tests. The cardiovascular segment is growing due to an increase in heart diseases.

Main Competitors

Looking at the dynamics of foreign medical manufacturer penetration in the Ukrainian market, European and Japanese companies are more aggressive than their U.S. competitors. They were the first to establish representative offices and focus on Ukraine as a potential market.

Domestic medical equipment production is not competitive on a global scale. Ukraine has some production capacity, but companies are generally under-capitalized and unable to compete with the high quality and relative low costs of imports.

Current Demand

Best prospects include:

- Diagnostic imaging equipment (ultrasound, computer tomography, magnetic-resonance tomography)
- Emergency medical equipment (ambulances, mobile hospitals)
- Operating rooms
- Surgical navigation systems
- Laser surgery devices
- Implantable cardiac devices, neurostimulation systems
- Dental equipment and materials
- Laboratory equipment, diagnostic point-of-care tests.

The Ukrainian market is receptive to high-quality, advanced diagnostic and therapeutic equipment. Innovative technologies such as laser-optics in vascular surgery, urology, gastroenterology, dermatology and neurosurgery; and new diagnostic devices are becoming more popular. Modern equipment offering ease of use and cost savings is required in the fields of micro-surgery, radiology and bio-medicine.

Registration Process

Registration is a requirement for the importation of medical equipment into Ukraine. It is performed by the State Service for Medicinal Products and Medical Devices under the Ministry of Health (MoH), and is based on evaluation of the product by expert testing agencies. Applications for registration must be submitted (on a standard form) to the State Service.

Ukraine moves towards harmonization with European standards in the field of medical equipment/devices. The Technical Regulation on medical devices was adopted in October 2, 2013. The new system will utilize national conformity assessments similar to those used by EU

regulators, and will also introduce the following requirements for Ukrainian medical device registrations:

- Foreign registrants must appoint Authorized Representatives based in Ukraine
- Expanded list of documentation and sample submissions required for registrations
- Manufacturing site inspections for Classes I, IIa, IIb and III
- Special symbols of national conformity will be required for medical devices imported into Ukraine on or after July 1, 2014
- National conformity certifications valid for five years

Barriers

Although the new Ukrainian registration system will bear many similarities to the CE Marking process for medical devices in Europe, no simplified or expedited market pathways are planned for devices already approved or cleared for sale in major markets such as Europe or the US. Manufacturers should also be aware that Ukrainian regulations will require inspection of facilities even if those sites are already ISO 13485-compliant.

According to current regulations, government tenders are to be non-discriminatory against foreign bidders, with some exceptions granted on a tender-by-tender basis. These exceptions give priority to domestic suppliers.

Trade Events

Public Health

September 29–October 1, 2015 • Kyiv, Ukraine • publichealth.com.ua/en

The largest medical equipment and pharmaceuticals trade show in Ukraine, including dental, clinical laboratory, and optical. Held annually. Organized by Premier Expo, part of the UK's International Trade Exhibitions Group.

United Arab Emirates

Summary

The Healthcare Sector remains among the priority sectors identified by the United Arab Emirates' government and, as a result, the UAE healthcare industry has displayed extraordinary growth and significant progress in the past few years. The government's focus on healthcare is aimed not only to diversify the oil-reliant economy but also to develop unprecedented healthcare infrastructure to ensure that adequate services are provided in the Emirates.

The World Health Organization determined that a third of adults in the UAE are obese, and one out of five people live with diabetes. As the incidences of lifestyle diseases increase, these populations, supported by relatively high levels of income, will demand greater quality of healthcare. Demand growth in this segment could act as an incentive for private investors to establish multi-disciplinary hospitals and specialized centers for complex diseases.

Healthcare is regulated at both the Federal and Emirate level. Federal level legislation dates back to the 1970s and 1980s and there are pending legislative reform initiatives in order to facilitate the development of the healthcare industry.

Market Entry

The United Arab Emirates (UAE) represents a major market for U.S. exports and serves as an important regional hub for U.S. companies conducting business throughout the Middle East, Africa and South Asia. Owing to rapid expansion of bilateral trade in recent years, the UAE has overtaken Saudi Arabia as the largest market for U.S.-made products in the Middle East.

Reflecting the country's role as a major regional commercial center, a significant portion of the UAE's import volume is ultimately re-exported. Dubai in particular plays a central role as a regional trade facilitation, logistics and tourism hub.

Statistics

Capital: Abu Dhabi
Population: 9,577,128
GDP (USD): 390 billion
Currency: UAE dirham (AED)
Language: Arabic

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In terms of foreign investment, the UAE is the second largest recipient of foreign direct investment in the Gulf region. According to investment experts, some of the biggest opportunities are likely to be found in healthcare projects which have already attracted major global companies such as General Electric and Siemens, both of which have large infrastructure business as well as being major suppliers of healthcare IT and diagnostic imaging technologies.

Initiatives such as the creation of free zones, including the two free zones, Dubai Health Care City (DHCC) and DuBiotech are an expected increase of FDI in general and investment in healthcare research in particular.

As a general rule, a foreign company intending to conduct business in the UAE must do so either by (a) incorporating a local entity “onshore,” (b) incorporating an entity in one of the UAE’s many free zones, (c) establishing a branch of representative office (either “onshore” within the UAE, or in one of the free zones, or (d) via a local commercial agent.

- Restrictions on foreign ownership limit foreign companies’ participation to a maximum of 49 percent of the equity in a UAE “onshore” company.
- While an entity within one of the UAE’s free zones can be wholly owned by a foreign company, as a general rule, such free zone entities may only conduct their business within the boundaries of the free zone. Accordingly, in order to distribute products throughout “onshore” UAE, the services of a local distribution agent are required.

Current Market Trends

Healthcare expenditure as percentage of GDP represented an estimated 3.4 percent in 2014, equal to USD 13.8 billion, and will continue at that level in the coming years. Per capita health expenditure will remain high regionally and globally, estimated USD 1,465 in 2014. Although spending increased by a 2009–14 CAGR of 8.3 percent, reports indicate that the UAE still needs to increase health expenditure, particularly in the Northern Emirates. The UAE is a zero-tax country, with excellent transportation and logistics infrastructure and is geographically well positioned to be the commercial hub in the region. These factors make it an attractive location for establishing a regional distribution center for medical devices. Healthcare is regulated at both the federal and Emirate level. Registration of medical devices is regulated by the UAE Ministry of Health. The regulation of medical devices in the UAE is aimed at maintaining a balance between product safety, quality and effectiveness.

Definition of Medical Devices

Products including accessories used in healthcare for diagnosis, prevention, monitoring or treatment of illness or handicap excluding drugs. Medical devices can be consumables, diagnostic imaging, dental products, orthopedic and prosthetic products, and patient aids.

Medical Device Regulations

All medical devices must be approved by the UAE Ministry of Health Drug Registration and Control Department. Imported medical devices will not be cleared by Customs unless a pre-approval for importation of the consignment is issued by MOH.

If the exporter company/manufacturer has no legal presence in the UAE, it will have to appoint a local representative to act on its behalf to register the devices. The local representative must be appointed by written contract stating the appointment of the local authorized representative by the company. The local representative should be licensed by the Ministry of Health.

Qualification of Registration of Medical Devices

An application to register a medical device in the UAE must be made by the device manufacturer or its local representative/distributor. The local representative/distributor must be formally authorized by the manufacturer to handle the application process and the manufacturer's legal obligations and responsibilities with regard to placing the medical device in the UAE market. The authorized representative/distributor must be available to interact between the medical device manufacturer and the Ministry of Health.

Supporting Documents to the Committee

The applicant must provide the committee with the following documents: Copies of all certificates related to ISO 9001:2000 standards; the ISO 13485:2003 standard attested and authenticated GMP (Good Manufacturing Practice) original certificate issued by the relevant health authorities at country of origin attested and authenticated; device description, intended use, directions for use, contraindications, warnings, precautions; specifications of material used in device manufacturing and packing; copies of certification and documents certifying conformity to product standards, safety, and quality systems in design and manufacturing; list of countries where it is marketed and details of regulatory status; a summary of "mandatory" reported problems with device since its introduction in the market; risk assessment comprising risk analysis, evaluation and reduction measures; detailed information on safety studies which includes pre-clinical and clinical studies, software studies, software validation studies where appropriate, and bibliography of published reports dealing with the device; stability studies; price information, such as ex-factory price; and post-market requirements, i.e., providing evidence of established procedures and systems for distribution records.

These documents may be submitted in English or Arabic. The applicant must declare that all submitted documents are true and that she will be fully responsible for the product and post-market plan submitted for complaint handling and recall and, that she will fully comply with the requirements of the Drug Control Department after the placing of the product in the market.

Main Competitors

The UAE market is totally dependent on imports for medical devices; while U.S. suppliers enjoy some advantages, including competitive prices, language, and exchange rate, European suppliers are aggressively gaining market share with their close proximity to the market and perceived better customer support.

Registration Process

Current medical device regulations in the UAE are based upon EU, Australian TGA and U.S. FDA regulation. Products with EU, Australian, FDA, Canada's TPP approval are eligible for a shortened registration process in the UAE.

Foreign countries wishing to export their products into the UAE must do so through a local representative or distributor who has a licensed medical store/entity from the MOH.

For example, for the medical devices registration: the appointed local distributor/representative must submit a medical device registration application form to the MOH Drug Control Department. If the application is approved, a registration number will be given, which will be valid for five years. The application can be written in either English or Arabic.

According to the MOH, approval process takes between 8–12 weeks after the application is submitted.

Barriers

The UAE Commercial Companies Law requires that each company established in the UAE have one or more UAE national partner(s) who hold at least 51 percent of the company's capital. Foreign companies may engage in a commercial agency arrangement whereby a foreign company is represented by a UAE agent to distribute, sell, offer, or provide goods or services within the UAE. The agent must either be a person holding UAE nationality or a company that is 100 percent owned by UAE nationals.

Trade Events

Arab Health 2016

January 25–28, 2016 • Dubai, UAE • arabhealthonline.com

Hospital Build 2016

June, 2016 • Dubai, UAE • hospitalbuild.com



United Kingdom

Summary

The UK's large and sophisticated healthcare market has a constant need for products and is very receptive to new and innovative technologies. It is divided between the National Health Service (NHS—USD 177 billion) and smaller private segment (USD 53 billion). The NHS is funded through taxation and provides free treatment at the point of delivery for the majority of its services. Its founding principle of good quality healthcare for all, regardless of wealth, is strongly supported by the majority of the population (2014 survey: 89 percent). Private healthcare is mainly funded through private medical insurance. Its strengths lie in the provision of secondary and tertiary care; fields not typically available through the NHS (cosmetic surgery); or where public health services are limited (elder care, dental). The nature of the market means that private sector growth is closely linked to public sector performance, policy and funding for core services.

The country's medical equipment market was valued at USD 9.5 billion in 2014. It is the world's sixth and one of Europe's largest medical equipment markets. The U.S. is the most important overseas source of medical devices, with an estimated 20 percent of share of the market in 2014. It is a leading supplier of diagnostic, dental, orthopedic equipment and high quality wound care products to the UK. A number of U.S. companies are very well-established in the UK and leading suppliers of technology and e-health systems.

The UK medical technology sector comprises of just over 3,100, mainly small to medium sized companies. They are evenly spread across the country with small clusters of companies situated in the Midlands and East of England. Radiotherapy equipment, neurology and cardiovascular devices were the top performing segments, in terms of turnover, in 2014. Other well performing segments included single use technology, in vitro diagnostic technology and orthopedic devices. The majority of domestically produced medical products are exported; hence the demand for products and the country's large import market.

Statistics

Capital: London
Population: 64.6 million
GDP (USD): 2.8 trillion
Currency: Pound Sterling (£/GBP)
Language: English

Contact

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Market Entry

The NHS, the principal purchaser of medical products, is traditionally regarded as one system, and receives funding from central government, but is essentially managed as four separate segments: NHS Wales, NHS Scotland, HSC Northern Ireland and NHS England. NHS England, the largest segment (82 percent of the UK population), is comprised of around 200 general practitioner-led (GP) clinical commissioning groups (CCG's), which plan and commission NHS services, such as hospital care or community health services, for their local patients; 166 acute trusts, which provide hospital services; 12 ambulance trusts; and 60 mental health trusts.

Most medical device procurement is done by acute trusts that have the choice of purchasing through centralized organizations such as NHS Supply Chain (www.supplychain.nhs.uk), which maintains a product catalog of "approved" medical products and services. Trusts may also buy individually, pool resources with each other for procurement decisions or work through collaborative procurement hubs. Companies favoring a direct approach can contact trusts or agencies, register on portals such as Supplying to the NHS (supplying2nhs.com), or search for contracts on the Contracts Finder site (www.gov.uk/contracts-finder). As it can be difficult to sell directly to the NHS from overseas, many U.S. exporters find it easier to form distribution partnerships with well-established local companies. This enables new entrants to take advantage of their partner's market expertise as well as their access to buyers and other decision makers within the NHS. Potential suppliers can approach private sector healthcare providers, such as HCA Healthcare or Spire Healthcare, directly about procurement opportunities.

Current Market Trends

- The UK's aging population is causing an increase in age-related health problems and demand for adequate social care. One way the NHS is seeking to address this is through the use of assistive technology which enables patients to self-monitor their health. The growing use of home technology is part of a trend towards a shift in healthcare provision from hospitals to community services, and the wider use of e-health technologies.
- Demand exists within the rehabilitation and orthopedic area due to government efforts to promote disabled and elderly independence.
- There continues to be a focus on preventative care in areas such as oral health, diet and fitness, to address the rise in "lifestyle-related" conditions such as diabetes and obesity.
- Within the dental market the private sector should continue to benefit from the shift of patients from the public sector to private providers. This is because the NHS limits the treatments it offers, while the private sector is able to offer more aesthetic and innovative treatments that patients are willing to pay for.
- Recent healthcare reform in England is creating opportunities for private sector health providers to supply more goods and services. For example, under the "any qualified

provider scheme” (AQP) NHS patients with can choose certain treatments or care from approved public or private providers. These services, regardless of provider, remain free at the point of delivery

Main Competitors

Many of the leading U.S. medical device and technology providers have subsidiaries in the UK. They include companies such as Baxter Healthcare, Medtronic, GE Healthcare, Cerner and Hyland. The UK medical device industry is still fragmented with many small companies selling specialist equipment and devices. Approximately 98 percent of companies are classed as SMEs.

Current Demand

Substantial resources are currently committed to treating several diseases:

- Cancer
- Alzheimer’s
- General mental illness
- Parkinson’s
- Diabetes
- Rheumatoid arthritis
- Obesity

Registration Process

Medical devices and medicines require an appropriate CE mark or marketing license, respectively, to be sold and marketed in the UK. The Medicines and Healthcare Products Regulatory Agency (mhra.gov.uk), an agency of the Department of Health, governs the regulation of medicines and devices.

Barriers

U.S. companies should not encounter any political or trade barriers to market entry. The UK adheres to EU procurement rules and conducts most buying through commercial negotiation. That said, the NHS faces considerable financial pressure and so will often make purchasing decisions based on price alone, rather than factoring in quality or patient outcomes. One hurdle that companies can face is the UK National Institute of Health and Clinical Excellence (NICE), which judges the clinical and cost-effectiveness of new and existing drugs, treatments, and medical devices. It provides the NHS with guidance on treatment strategy and influences procurement decisions by stating which products are reimbursable on the NHS.

Trade Events

Health and Care Innovation Expo

Manchester, England • September 2–3, 2015 • www.england.nhs.uk/expo

England's National Health Service conference and exhibition.

EHl Live 2015

Birmingham, England • November 3–4, 2015 • ehilive.co.uk

Health IT conference and exhibition.

UK e-Health Week

London, England • April 19–20, 2016 • ukehealthweek.com

Health IT conference and exhibition.

Naidex

Birmingham, England • April 26–28, 2016 • naidex.co.uk

Home, disability, and rehabilitation exhibition.

MEDTEC UK

London, England • June 21–22, 2016 • medtecuk.com

Exhibition for the medical devices manufacturing industry.

The Dentistry Show

Birmingham, England June 22–23, 2016 • thedentistryshow.co.uk

Dental conference and exhibition.

Health+Care 2016

London, England • June 29–30, 2016 • healthpluscare.co.uk

Care commissioning conference and exhibition.



Uruguay

Summary

Uruguay imports almost all its medical equipment. Major market opportunities are for new, technologically advanced supplies and equipment, particularly in the areas of non-invasive procedures, ultrasound, magnetic resonance imaging, and CT scans. All products must be registered with the Ministry of Public Health by a duly approved and registered local representative.

Market Entry

Approximately 35 percent of Uruguay's total medical equipment imports are for the public sector and 65 percent are for the private sector.

Customs duties and other taxes for medical equipment range from 0–20 percent. The only products that require special processing are those associated with orthodontics, on which a 5 percent Professional and University Orthodontics tax is applied.

Current Market Trends

With the exception of low-tech monitors, almost none of the medical equipment and surgical supplies sold in Uruguay is produced locally. Major market opportunities are for new, technologically advanced supplies and equipment, particularly in the areas of non-invasive procedures, ultrasound, magnetic resonance imaging, and CT scans. Buyers turn to U.S. suppliers for cardio instruments and imaging, as well as for blood transfusion, IV, and surgery equipment.

Statistics

Capital: Montevideo
Population: 3.3 million
GDP (USD): 57.6 billion (2014)
Currency: Uruguayan Peso (UYU)
Language: Spanish

Contact

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Main Competitors

The majority of products for local distribution are imported from Argentina, Brazil, Mexico, the EU, and the United States. Asian countries, and particularly China, have been increasing their market share.

Current Demand

Cardiovascular problems are the most common cause of death amongst the population over 45 years old, with malignant tumors as the second leading source of mortality.

Imports of refurbished medical equipment are authorized and many times preferred by small private clinics (refurbished protocol must be presented with registration request).

Registration Process

All medical products have to be registered and approved by the Ministry of Public Health (MPH). The Ministry's Division of Control is responsible for all registrations. With prior authorization from the MPH, orthopedic prosthesis as well as other items for handicapped patients or institutions may be exonerated from tariff duties. Only local and duly approved companies may register medical equipment and supplies.

Barriers

Local importers and distributors, as well as health institutions, face challenges due to the requirement that the purchase of any new or replacement of old equipment valued at more than USD 15,000 needs the MPH's prior approval and this process may take up to 18 months.

Trade Events

Medical conventions may include exhibits, but the exhibits are primarily from the companies that are sponsoring the event. Most local importers/distributors/physicians attend shows in Brazil, Argentina, and the United States.

Available Market Research

- Medical Equipment Overview
- Clinical Lab Equipment and Supplies
- Registration Process Brief (Medical equipment and Pharmaceuticals)

Resources

- Healthcare Procurement, bit.ly/1D9R2qY
- Government Health Plans, bit.ly/1OCMZnp

Vietnam

Summary

Vietnam represents a potentially large healthcare, medical equipment, and device market. Identified as one of the national development priorities, the Vietnamese public healthcare sector has received increasing government budget allocations as well as interest from the private sector. Vietnam receives a large amount of international aid in the form of loans and donated medical equipment. A number of small projects are currently taking place in Vietnam, including those funded by the World Bank and the EU.

The market for healthcare technology in Vietnam is large, but not without difficulties. The medical device market is expected to grow at 10.3 percent annually. In 2011, the market for medical equipment and supplies was estimated at USD 599 million, or USD 7 per capita. It is expected that the device market will continue to expand strongly at 15.2 percent. The outlook for the Vietnamese market is around USD 1.2 billion in 2016, although the per capita rate will remain low.

Market Entry

Until recently, foreign medical device companies were only allowed to sell their devices through local wholesale distributor companies. These local companies would then distribute to smaller distributors within their network. This restriction was removed in 2008; some foreign medical device companies have now set up their own distribution systems in Vietnam.

Statistics

Capital: Hanoi
Population: 92 million
GDP (USD): 186 billion
Currency: Vietnamese dong (VND)
Language: Vietnamese

Contact—Hanoi

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Current Market Trends

The system needs a wide variety of medical equipment for such areas as cardiovascular, liver cancer, diabetes, and orthopedics. The best sales prospects for this market include imaging diagnostic equipment (i.e., X-ray machines, CT Scanners, Color Ultrasound machines, Magnetic Resonance Imaging machines), operating theaters and sterilizing equipment, patient monitoring equipment and emergency equipment.

Main Competitors

The main sources are from the U.S., Germany and Japan. In addition, Taiwan, Italy, France and South Korea also account for significant shares.

Local production is extremely limited in terms of value, but volume levels suggest the foundation for ascent up the value chain. There are presently 50 domestic companies making approximately 600 products officially licensed by MOH. They tend to produce products such as hospital beds, scalpels, cabinets, scissors, and disposable supplies. They also tend to offer limited or no warranty or after-sales services, especially in isolated areas.

Current Demand

It is estimated that 90.7 percent of the medical devices utilized in both public and private health facilities are supplied by imports. There are four main classes of medical device purchasers. The largest are government-funded hospitals, which counts for 70 per cent of the market. Foreign-owned hospitals and clinics also are large purchases; however, these facilities usually purchase supplies from their sponsoring country. Local private hospitals will exhibit the strongest growth, while research and educational institutions will also account for some demand. The five year health sector development plan 2011–15 makes equipping hospitals with a minimum provision of 60 percent of common medical equipment a key task.

The Vietnamese health care system has an estimated 1,062 state hospitals, 100 local private hospitals and 15 foreign invested hospitals that total to an estimated 145,000 beds. There are 273 new hospitals at some stage of the planning process with slightly over half of these projects located in Southern Vietnam.

Used equipment:

Most imports of used and refurbished medical equipment are strictly controlled by the Ministry of Health (MOH). Decision 2019/1997/QĐ-BKHCNMT dated December 1, 1997, stipulates that the Ministry of Science, Technology, and Environment (MOSTE) must inspect and certify all imports of used medical equipment. Such used medical equipment must retain at least 80 percent of its life expectancy and must have fuel or electricity consumption ratings that do not exceed 110 percent of the consumption of newer versions of the equipment. Because of the restriction, local companies are generally not willing to deal with foreign

suppliers of used and refurbished equipment. In practical terms, MOH accepts used equipment for donation purposes only.

Registration Process

MOH determines the guidelines for medical device purchase for all health systems in Vietnam. Within the MOH, the Department of Medical Equipment and Construction is in charge of medical devices. The Ministry of Science and Technology (“MOST”) performs some regulatory functions for domestically made medical devices.

The registration process for medical devices manufactured within Vietnam is different than those that are imported. Devices which are imported are not required to be registered. Instead, a product specific import license is utilized.

Recently, MOH has submitted the Draft Decree on importing medical equipment to the government office. The Decree, which is expected to come into effect in 2015, is aimed to tighten inspections and supervision of medical devices imported into Vietnam. All devices imported into Vietnam are required to be new, and importers need a license to operate in the field. The MOH will also build a center in charge of supervising the quality of foreign-made medical equipment before it is imported into Viet Nam.

Trade Events

Pharmed & Healthcare Vietnam

September 23–26, 2015 • Ho Chi Minh City, Vietnam • pharmed.vn/en

VIETNAM MEDI-PHARM EXPO

August 20–22, 2015 • Ho Chi Minh City, Vietnam • medipharmexpo.com/eng
international hospital, medical, and pharmaceutical exhibition.

Available Market Research

- Medical Device Market—Department of Medical Equipment and Health Works
- Pharmaceuticals and Healthcare Report—BMI.
- Vietnam Healthcare Sector Overview—Stoxplus

Subsector Reference Chart

Rating Definitions																
	1 Little to no probability of success for U.S. exporters															
	2 More challenges than opportunities															
	3 More opportunities than challenges															
	4 Very high probability of success for U.S. exporters															
Medical Devices—General	Medical Devices—Monitoring Equipment	Medical Devices—Orthopedic	Medical Devices—Surgical	Medical Capital Equipment	Biomedical	Clinical Chemistry Diagnostics	Dental	Dietary Supplements	Drugs & Pharmaceutical	Health IT	Laboratory Equipment	Used Equipment	Aging and Nursing Care	Consulting Services	Veterinary Medicine	
Europe																
Austria	4	4	3	4	3	4	4	3	2	4	4	4	2	3	2	3
Belgium	3	3	3	3	3	3	3	3	1	3	3	3	2	3	3	2
Bulgaria	3	3	3	3	2	4	3	3	3	3	3	2	2	2	2	3
Croatia	4	4	4	4	3	3	4	4	4	4	3	3	1	3	4	3
Cyprus	4	3	3	4	3	4	3	3	3	2	4	2	1	2	2	2
Czech Republic	4	4	3	4	2	3	3	3	2	3	3	3	2	3	2	4
Denmark	3	3	2	3	3	3	3	2	1	3	4	3	1	–	1	2
Finland	3	3	3	3	2	3	3	3	2	2	4	3	1	3	2	3
France	3	3	3	2	2	2	4	3	2	4	3	3	1	3	1	2
Germany	3	3	3	3	2	3	3	3	2	2	3	3	2	3	3	3
Greece	3	2	3	3	2	2	3	3	3	3	3	2	1	–	3	2
Hungary	3	3	2	2	2	3	4	3	3	3	4	3	2	–	2	2
Ireland	3	2	2	2	1	2	2	2	2	3	2	2	3	3	2	3
Italy	3	3	3	3	2	3	3	3	2	3	2	3	1	2	2	2
Macedonia	3	4	3	3	3	3	3	3	2	2	3	4	2	2	3	3
Netherlands	4	3	3	3	4	3	3	3	2	3	4	3	1	3	2	3
Norway	4	4	3	3	3	3	3	3	1	2	4	3	1	–	2	3
Poland	2	2	2	2	1	2	2	3	2	2	2	2	2	3	2	2
Portugal	3	3	3	3	3	3	3	3	3	3	4	3	2	–	3	3
Romania	3	3	3	2	2	2	3	3	3	3	3	3	2	3	2	–
Russia	2	2	3	2	2	3	2	4	3	2	3	3	2	–	3	4
Slovak Republic	3	3	2	3	2	3	3	3	2	3	4	3	2	3	2	2
Spain	2	2	2	2	2	3	2	2	1	2	2	2	1	2	1	2
Sweden	3	3	2	3	2	3	3	3	2	3	4	3	1	2	2	2
Turkey	4	2	3	4	4	4	4	4	2	3	4	3	1	2	2	3
United Kingdom	3	3	3	2	2	3	3	3	2	2	3	3	2	3	3	3
Ukraine	3	3	2	4	3	3	3	3	2	3	3	3	2	2	1	2

Rating Definitions 1 Little to no probability of success for U.S. exporters 2 More challenges than opportunities 3 More opportunities than challenges 4 Very high probability of success for U.S. exporters	Medical Devices—General	Medical Devices—Monitoring Equipment	Medical Devices—Orthopedic	Medical Devices—Surgical	Medical Capital Equipment	Biomedical	Clinical Chemistry/Diagnostics	Dental	Dietary Supplements	Drugs & Pharmaceutical	Health IT	Laboratory Equipment	Used Equipment	Aging and Nursing Care	Consulting Services	Veterinary Medicine
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Western Hemisphere

Argentina	3	3	2	2	3	3	3	2	1	2	2	3	1	2	1	1
Bolivia	4	4	3	3	4	2	2	4	2	3	2	4	4	3	2	3
Brazil	3	3	2	3	3	3	3	2	3	2	4	3	1	4	2	4
Canada	4	4	3	3	3	3	3	2	2	3	3	3	2	3	2	
Chile	3	3	3	3	1	3	2	2	1	1	2	2	1	1	1	3
Colombia	4	3	3	4	3	3	2	3	3	2	3	3	1		1	3
Costa Rica	4	4	4	4	1	3	2	4	1	2	2	2	1		1	2
Dominican Republic	3	4	4	3	3	2	3	3	3	2	3	3	2	2	3	2
El Salvador	3	3	3	3	3	1	3	3	3	3	2	3	2	1	1	3
Guatemala	4	4	3	3	3	2	3	3	3	3	3	3	2	3	4	4
Mexico	3	3	3	3	3	3	3	2	2	2	4	3	3	1	3	3

Middle East/Africa

Angola	4	3	2	4	3	3	4	4	1	4	3	4	2	3	4	4
Egypt	3	3	3	4	2	3	3	3	3	3	2	3	1	—	2	3
Ghana	2	3	3	3	3	2	3	3	3	3	2	3	4	—	3	2
Israel	4	4	4	4	4	4	3	3	3	4	3	3	1	3	2	4
Jordan	3	3	4	2	3	3	3	2	3	3	4	3	1	2	2	2
Kenya	4	4	4	4	4	3	3	3	2	3	3	3	4	2	2	2
Kuwait	4	4	4	4	4	4	4	4	4	4	3	4	1	4	3	2
Libya	4	4	4	4	4	4	4	—	—	—	—	—	—	—	—	—
Mauritius	3	3	3	3	3	3	3	3	3	3	3	3	1	2	3	3
Morocco	3	3	3	3	2	3	2	3	3	2	2	3	1	1	2	—
Nigeria	4	3	3	2	3	2	4	1	4	2	1	3	4	2	2	2
Oman	3	3	3	3	3	3	3	2	2	2	3	3	3	3	3	2
Saudi Arabia	4	4	4	4	4	2	4	4	1	4	4	4	1	2	3	3
South Africa	3	3	2	3	2	3	2	3	1	1	2	2	1	2	1	3
United Arab Emirates	4	4	4	4	3	3	3	3	2	3	3	3	2	2	2	2

Rating Definitions 1 Little to no probability of success for U.S. exporters 2 More challenges than opportunities 3 More opportunities than challenges 4 Very high probability of success for U.S. exporters	Veterinary Medicine	Consulting Services	Aging and Nursing Care	Used Equipment	Laboratory Equipment	Health IT	Drugs & Pharmaceutical	Dietary Supplements	Dental	Clinical Chemistry Diagnostics	Biomedical	Medical Capital Equipment	Medical Devices—Surgical	Medical Devices—Orthopedic	Medical Devices—Monitoring Equipment	Medical Devices—General

Asia/Southeast Asia

Australia	4	4	4	4	4	4	4	4	2	3	3	4	1	4	2	4
Brunei	3	3	3	3	3	2	2	2	2	3	3	3	1	1	3	
China	3	2	3	3	2	3	3	3	2	2	3	3	1	3	2	4
Hong Kong	4	4	4	4	3	4	4	4	3	3	3	3	1		2	3
India	4	3	4	4	4	3	4	3	3	3	3	3	3	2–3	2	3
Indonesia	3	4	3	3	4	3	3	3	3	2	3	3	1	2	2	2
Malaysia	3	3	4	3	3	3	3	3	3	3	3	3	1	3	2	3
Japan	3	2	3	3	2	3	2	2	2	3	3	3	1		2	2
Korea, Republic of	3	2	3	3	2	2	2	3	3	2	2	2	1	2	1	2
New Zealand	3	3	3	3	3	2	2	2	3	3	2	3	1	3–4	1	3
Philippines	3	3	3	3	2	3	3	2	2	2	2	3	3	1	1	2
Singapore	–	3	3	4	3	3	3	3	3	3	3	3	3	1	3	2
Taiwan	3	3	3	3	2	3	3	3	3	3	3	3	1	3	2	2
Thailand	4	4	4	4	2	3	4	2	2	3	4	4	1	2	1	3

Certification Reference Chart

Rating Definitions 1 Little to no probability of success for U.S. exporters 2 More challenges than opportunities 3 More opportunities than challenges 4 Very high probability of success for U.S. exporters	Requires FDA Certification?	Accepts FDA Certification?	Requires CE Mark Certification?	Accepts CE Mark Certification?	Other Certification Required?	Other Certification Accepted?	Certifying Body	Preferred Certification
Europe								
Austria	No	No	Yes	Yes	No	No	tuev.at	Yes
Belgium	No	No	Yes	Yes	Yes	Yes	fagg-afmps.be	Yes
Bulgaria	No	No	Yes	Yes	GMP ¹	Yes ²	All European	Yes
Croatia	No	No	Yes	Yes	No	No	halmed.hr	CE
Cyprus	No	No	Yes	Yes	No	No	EU Notified Bodies	CE
Czech republic	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Denmark	No	No	Yes	Yes	No	No	Dansk Standard	CE
Finland	No	No	Yes	Yes	Yes ³	No	valvira.fi/en	CE
France	No	No	Yes	Yes	No	No	www.gmed.fr	Yes
Germany	No	No	Yes	Yes	RoHS/WEEE	Yes	EU Notified Bodies	No
Greece	No	No	Yes	Yes	Yes ³	No	EOF, ELOT, EKEVYL	Yes
Hungary	No	No	Yes	Yes	Yes ⁴	Yes	mkeh.gov.hu	CE
Ireland	No	Yes	Yes	Yes	Yes ⁴	No	hpra.ie	CE
Italy	No	Yes	Yes	No	Yes	N/A	Yes	CE
Macedonia	No	No ⁵	Yes	Yes	No	Yes ⁶	N/A	CE
The Netherlands	No	No	Yes	Yes	No	N/A	Yes	Yes
Norway	No	No	Yes	Yes	No	No	Nemko, Justervesenet, Nordic Dental, DnV	Yes
Poland	No	No	Yes	Yes	Yes	No	urpl.gov.pl ; pcbc.gov.pl	CE
Portugal	No	Yes	Yes	Yes	No	No	N/A	CE
Romania	No	No	Yes	Yes	Maybe	No	EU Notified Bodies	N/A
Russia	No	No	No	No	Yes	No	Yes	N/A
Slovak Republic	No	Yes	Yes	Yes	Yes	Yes	sukl.sk	Yes
Spain	No	No	Yes	Yes	Yes	Yes	aged.es	CE
Sweden	No	No	Yes	Yes	No	No	lakemedelsverket.se	CE
Turkey	No	No ⁷	Yes	Yes	No	No	EU Notified Bodies; global.tse.org.tr	CE
United Kingdom	No	No	Yes	Yes	Maybe	No	mhra.gov.uk	—
Ukraine	No	No	No	No	Yes ⁸	N/A	Yes ⁸	—

Rating Definitions 1 Little to no probability of success for U.S. exporters 2 More challenges than opportunities 3 More opportunities than challenges 4 Very high probability of success for U.S. exporters	Requires FDA Certification?	Accepts FDA Certification?	Requires CE Mark Certification?	Accepts CE Mark Certification?	Other Certification Required?	Other Certification Accepted?	Certifying Body	Preferred Certification
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Western Hemisphere

Argentina	Yes	Yes	–	–	Yes ⁸	–	ANMAT	FDA
Bolivia	No	No	No	No	Yes ⁸	No	Yes ⁸	–
Brazil	Yes	Yes	No	Yes	Yes	Yes	Anvisa/Inmetro	Yes
Canada	No	No	No	No	Yes	No	Health Canada	–
Chile	No ⁹	No ⁵	No ⁹	No ⁵	Maybe ¹⁰	No	Instituto de Public Health	FDA, CE
Colombia	Yes ¹¹	No ¹¹	–	–	–	–	www.invima.gov.co	–
Costa Rica	Yes	–	–	–	–	–	Yes ⁸	FDA
Dominican Republic	No	Yes	No	Yes	No	Yes	N/A	N/A
Guatemala	No	Yes	No	Yes	No	–	Yes ⁸	FDA, CE
Mexico	Yes	No	No	No	Yes	No	COFEPRIS	N/A
Uruguay	No	No	No	No	Yes	No	Yes ⁸	N/A

Middle East/Africa

Egypt	Yes	Yes	Yes	Yes	ISO	ISO	Yes ⁸	Yes ⁸
Ghana	Yes ¹²	Yes ¹³	No ¹⁴	Yes	Yes ¹³	Yes ¹³	Yes ¹⁵	FDA, CE, Ghana
Israel	Yes	Yes	Yes	Yes	Yes ¹⁶	Yes	Yes ⁸	FDA
Jordan	Yes	Yes	Yes	Yes	ISO	ISO	Yes ¹⁵	Yes ¹⁵
Kenya	No	No ⁵	No	No ⁵	Yes ^{8,10}	N/A	Yes ⁸	Yes ⁸
Kuwait	Yes	Yes	Yes	Yes	ISO	ISO	Yes ⁸	Yes ⁸
Nigeria	Yes	Yes	Yes	Yes	Yes	–	SONCAP (equipment); NAFDAC (food/drugs)	–
Oman	Optional	Yes	No	Yes	No	No	Yes ⁸	N/A
Saudi Arabia	Yes	Yes	Yes	Yes	ISO	Yes ¹⁷	Yes ¹⁵	FDA, CE, GHTF
South Africa	No	Maybe	Yes	Yes	Yes	No	Yes ⁸	CE
United Arab Emirates	Yes	Yes	Yes	Yes	ISO	ISO	Yes ⁸	Yes ⁸

Rating Definitions 1 Little to no probability of success for U.S. exporters 2 More challenges than opportunities 3 More opportunities than challenges 4 Very high probability of success for U.S. exporters	Requires FDA Certification?	Accepts FDA Certification?	Requires CE Mark Certification?	Accepts CE Mark Certification?	Other Certification Required?	Other Certification Accepted?	Certifying Body	Preferred Certification
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Asia/Southeast Asia

Australia	No	No	No ⁵	Yes	Yes ^{10,8}	–	Yes ⁸	–
China	Yes	No	No	No	No	No	SFDA	FDA
Hong Kong	No	Yes	No	Yes	No	Yes	Yes ⁸	Yes
India	Yes	Yes	Yes	Yes	No	N/A	<i>cdsco.nic.in</i>	N/A
Indonesia	Yes	Yes	No	Yes	Yes ¹⁸	No	ISO, EU	FDA
Japan	No	No	No	No	N/A	N/A	Yes ^{8,10}	N/A
Korea, Republic of	No	No	No	No	–	–	Yes ⁸	–
Malaysia	No	Yes	No	Yes	Maybe	Yes	Yes ⁸	Yes
New Zealand	No	No	No	No	N/A	N/A	Yes ⁸	–
The Philippines	No	No ⁵	Yes	Yes	–	Legislation pending	Yes ⁸	–
Singapore	No	Yes	No	Yes	No	Yes ¹⁹	Health Sciences Authority	Yes
Taiwan	No	Yes	No	Yes	Yes ¹⁸	ISO 13485	Yes ⁸	N/A
Thailand	Yes	Yes	Yes	Yes	Maybe ¹⁰	ISO 9001; ISO 13485	Yes ^{8,15}	FDA
Vietnam	Yes	Yes	Yes	Yes	Yes	N/A	Yes ⁸	FDA

1 WEEE for electronic elements

2 All European certifications accepted

3 Notify national certifying body about high-risk devices

4 National licensing office

5 Having this certification will assist with receiving preferred certification

6 ISO 9001; ISO 13485; ISO 14001

7 Certified devices preferred in marketplace

8 National health ministry or similar organization

9 Certification not required; however, limited or no opportunity without certification

10 Depends on product

11 Not as final certification

12 Company must also be in good standing

13 Local registration and representation also required

14 Not unless company is based in EU

15 National food and drug authority/administration

16 Electric safety testing

17 One of the GHTF founding member jurisdictions

18 Additional documentation also required

19 Australian, Canadian, and Japanese Health Ministries



Contacts

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